THE REGULATION OF COMPLEMENTARY AND ALTERNATIVE MEDICINE IN NEW ZEALAND

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Acknowledgements

And the candle by the light of which she had been reading that book filled with anxieties, deceptions, grief and evil, flared up brighter than ever, lit up for her all that had once been darkness, sputtered, grew dim and went out for ever.

Leo Tolstoy, Anna Karenina

Much like the transmogrification of Anna Karenina from a pinnacle of humanity, to a dark and tumultuous individual, so too has this thesis had its way with me; taking me to ecstasies and agonies previously unimaginable. For the little sanity that remains, and for the present tome, a number of people must be heartily thanked.

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For my father

With much love and unending gratitude

Abstract

There is little understanding of, or information about, CAM products, their use, or multifarious issues surrounding them in New Zealand. It is therefore unsurprising that NZ has lacked effective CAM product regulation for decades. Following a review of surrounding legislation, and a preliminary investigation into CAM product prevalence and perceptions, this research proposes new legislation for the regulation of CAM products, which takes a forward-looking, evidence-based approach to succeed where numerous other proposals have failed.

CAM products are effective unregulated in New Zealand, with the Dietary Supplements Regulations 1985 being sorely outdated, and every new proposal for the past three decades failing to come to fruition. As a result, general legislation like the Fair Trading Act 1986 is used to handle misleading or deceptive conduct in relation to CAM products, although its regulation of these products is inherently limited.

The two pieces of quantitative research in this thesis consider the habits and perceptions of New Zealanders around CAM products; first studying students, and second broadening the scope to collect data from a representative sample of New Zealanders. With 80% of New Zealanders having used CAM products, and a significant number being misled by the labelling and packaging on these products, new regulations around CAM products must address these issues to protect consumers.

This thesis proposes a new piece of legislation for the risk-based regulation of CAM products in NZ. Through adaptation of regulatory models and provisions utilised in other legislation, this proposed CAM Products Bill establishes an effective risk-based approach, which categorises CAM products into three tiers, plus a black-list for prohibited ingredients or products. This is a pre-approval scheme that links the evidence, safety, and research on the CAM product, to the fee structure, indirectly encouraging industry research and development into safe, quality and effective CAM products. Additionally, this Bill proposes a sound administrative structure and effective enforcement measures which have a history of use with CAM products.

Ultimately, this proposed legislation will fill the void which currently exists around CAM product regulation in NZ, particularly following the withdrawal by the new Labour Government of the Natural Health and Supplementary Products Bill in November 2017. It also addresses systemic problems of an information deficit by incentivising research into CAM products, and regulating in a manner that promotes scientific evidence, safety, efficacy, honest information for consumers, and high-quality CAM products through soft-touch risk-based CAM product legislation.

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Glossary of Acronyms & Abbreviations

ANZFSC	Australia New Zealand Food Standards Code 2002
ANZTPA	Australia New Zealand Therapeutic Products Agency
CAM	Complementary and Alternative Medicine
CC	Commerce Commission
CGA	Consumer Guarantees Act 1993 (New Zealand)
DALY	Disability Adjusted Life Years
DC	District Court (New Zealand)
DSRs	Dietary Supplements Regulations 1985 (New Zealand)
FA	Food Act (New Zealand)
FSANZ	Food Standards Australia New Zealand
FTA	Fair Trading Act 1986 (New Zealand)
GMP	Good Manufacturing Processes
HBC	Health Benefit Claim
HC	High Court (New Zealand)
LD_{50}	Lethal Dose for 50% of a Population
MA	Medicines Act 1981 (New Zealand)
Medsafe	New Zealand Medicines and Medical Devices Safety Authority
MoDA	Misuse of Drugs Act 1975 (New Zealand)
MoH	Ministry of Health
MP	Member of Parliament
MRs	Medicines Regulations 1984 (New Zealand)
NHSP	Natural Health and Supplementary Product
NHSPB	Natural Health and Supplementary Products Bill 2011 (New Zealand)
NOAEL	No Observable Adverse Effect Level
NSAID	Nonsteroidal Anti-Inflammatory Drug
NZ	New Zealand
PHARMAC	Pharmaceutical Management Agency
TC	Therapeutic Claim
TGA	Therapeutic Goods Administration (Australia)
TTMRA	Trans-Tasman Mutual Recognition Agreement 1998
UK	United Kingdom
USA	United States of America
YLD	Years Lived with a Disability
YLL	Years of Life Lost

1 Introduction

By definition … alternative medicine …
has either not been proved to work
or been proved not to work.

Do you know what they call alternative medicine that's been proved to work?
Medicine.[1]

Why does the regulation of complementary and alternative medicine (CAM) products matter?

CAM product regulation is not perceived to be a problem by the general public, and therein lies the issue. Typical comments might be: 'CAM products are something someone else takes, but not *me*. I just take my Vitamin C tablets when I feel a cold coming on, my iron pills when I am feeling a bit tired, and occasionally some arnica cream on a bruise, because my grandmother swore by it. *Even if* these are CAM products, they have to be regulated somehow, and the worst that could happen is they do nothing, right?'

During this research, innumerable conversations like this indicated two things. There exists a pervasive Antipodean (if not more widespread), laissez-faire attitude towards CAM products, that they are regulated somehow, because that is just the way things are: foods are regulated, medicines are regulated, so CAM products must be too. Secondly, public belief in their effect ranges from the naïve 'they might do something, but at least they will not harm me', to the actively illogical 'it is a remedy derived from plants that this particular culture has being using for hundreds of years, therefore it is natural, and must be safe'.

1.1 Complementary and Alternative Medicine

The truth about regulation of CAM products in NZ is somewhat more limited than the public might think. The New Zealand (NZ) regulations, the Dietary Supplements Regulations (DSRs) 1985, predate even the term 'complementary and alternative medicine', and given the Regulations' age and limited scope, they are all but redundant. Consequently, CAM products proliferate relatively unchecked throughout the NZ market, generating huge profits in a $1.4 billion industry,[2] and frequently making illegal therapeutic claims (TCs) about everything from relieving headaches, to treating cancer.[3]

[1] Tim Minchin "Tim Minchin's Storm the Animated Movie" (Film, 7 April 2011) YouTube <www.youtube.com>.
[2] Natural Products New Zealand "Report: Natural Products Industry a Signficant Contributor to NZ's Economy" (press release, 19 February 2015), at 1.
[3] Ministry of Health *Regulatory Impact Statement: The Development of a Natural Health Products Bill* (June 2011 2011), at 5-6.

Unfortunately, the idea that these products or this industry is regulated is a fallacy, with almost 20 years of proposals for a new CAM product regulatory system, but nothing to show for it. Furthermore, there is next to no impartial scientific information on the safety, or quality of CAM products in NZ, let alone their efficacy, and the little international evidence which exists suggests that product contamination, and the use of fillers or unlisted ingredients may be relatively common.[4]

New Zealanders have perhaps the highest affinity for CAM products in the 'western world', but are put at greater risk by the lack of regulation, and dearth of information surrounding CAM products in NZ. This thesis delves into the problems that have stymied new regulations, as well as scratching the surface of the information deficit, in order to put forward an informed, effective proposal for the regulation of CAM products in NZ.

1.2 Definitions

This section defines three key terms upon which this thesis is built. For the most part, important terms are defined within the thesis as they arise. However, it is necessary to consider what 'complementary and alternative medicine products' are, as well as detailing the scope of 'dietary supplements', and 'traditional medicine', to lay the foundations for this thesis.

Before defining these two terms, the term 'natural' must be debunked and its misappropriation in the medium of alternative healthcare highlighted. Except where unavoidable from its use in legislation like the Natural Health and Supplementary Products Bill 2011[5] (NHSPB) or in reference to other sources, the term 'natural' will not be employed in this thesis when considering CAM products, as it engenders what has been referred to as the 'naturalistic fallacy'.[6] That is the idea that because a product is 'natural' it is ipso facto safe. Aside from that being patently incorrect, it also belies the fact that not all CAM products are 'natural' within the ordinary meaning of the word – namely that they are not "existing in or caused by nature".[7]

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[4] Steven G Newmaster and others "DNA barcoding detects contamination and substitution in North American herbal products" (2013) 11 BMC Medicine 222.
[5] Natural Health and Supplementary Products Bill 2011 (324-2).
[6] Professor Sir Peter Gluckman "Submission to the Health Committee on the Natural Health Products Bill 2011" (February 2012) at 1.
[7] *The New Zealand Oxford Dictionary* (1st ed, 2005, online ed), 'natural'.

1.2.1 Complementary & Alternative Medicine Products

"A clear, objective and neutral … definition of [complementary and alternative medicine] is the first requirement for any reasoned debate and discourse…",[8] however it remains one of the major problems of this area due to disagreement on the appropriateness of the term 'complementary and alternative medicine', let alone defining what the term incorporates.

For the purposes of this thesis, it is simplest to first cover what CAM does not include, before delving into a definition and details of what it does include. This thesis is concerned with the regulation of CAM products, not CAM modalities or practices. The regulation of CAM modalities and the practitioners involved in those practices requires a different approach to the regulation of CAM products, and for that reason, neither this definition, nor this thesis includes discussion of CAM practices; except where absolutely necessary for the bigger picture. The second exclusion is that CAM products do not include medicines. Throughout this thesis, the term 'medicine' in isolation refers to conventional medicine, or evidence-based medicine; again terms which have broadly unsatisfactory definitions,[9] but nevertheless are generally comprehended as being distinct to CAM products insofar as 'western countries' are concerned. As shall be seen, despite excluding 'medicine' from the definition of CAM products, there remains an unavoidable overlap in practice; one which is especially pronounced in the present NZ regulatory scheme.[10]

There are multiple different approaches to defining 'complementary and alternative medicine'.[11] The World Health Organization defines 'complementary' and 'alternative' medicine as two separate terms "…used inter-changeably with traditional medicine in some countries. They refer to a broad set of health care practices that are not part of the country's own tradition and are not integrated in to the

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[8] Terry S. H. Kaan "Traditional, complementary, and alternative medicine" in Yann Joly and Bartha Maria Knoppers (eds) *Routledge Handbook of Medical Law and Ethics* (Routledge, Oxford, 2015) 419, at 419.

[9] Despite the term 'evidence-based medicine' being relatively common-place, it is estimated that approximately 20% of conventional medicine is actually scientifically proven; R. Imrie and D.W. Ramey "The evidence for evidence-based medicine" (2000) 8(2) Complementary Therapies in Medicine 123. Similarly, CAM is now widely taught in American medical schools and a number of modalities and products are part of mainstream medical tradition in some European countries; Katherine R Ellena "The uncritical enthusiasts versus the uninformed sceptics: Regulation of complementary and alternative medicines" (2005) 13(1) JLM 106, at 107.

[10] See Chapter 3.

[11] For example, the House of Lords Select Committee inquiry into CAM opted not to present a definition, due to a lack of agreement for a single definition, and instead they presented a list of therapies; House of Lords, Science and Technology Committee *Sixth Report: Complementary and Alternative Medicine* (online ed, 21 November 2000), Kaan, above n 8, at 421. Another common approach has been defining CAM by what it is not, namely that it has nothing to do with conventional or mainstream medicine; at 420.

dominant health care system."[12] While this definition is all-encompassing, it lacks clarity and applicability due to its focus on practices, its breadth and consequent abstraction.

The United States of America (USA) National Center for Complementary and Integrative Health also defines 'complementary' and 'alternative' medicine separately: "If a non-mainstream practice is used together with conventional medicine, it's considered 'complementary'. If a non-mainstream practice is used in place of conventional medicine, it's considered 'alternative'."[13] Although these definitions are objectively correct, they fail to provide a useable definition for 'CAM' in the context of the host of heterogeneous products that the term encompasses in this thesis.

Some commentators argue that CAM is largely a social construct, which must take account of the situation in different contexts.[14] In the context of this thesis, the following definition is posited, which incorporates some elements from the many commentators, while attempting to maintain sufficient flexibility for a broad study into the regulation of CAM products.

CAM products are not usually conventional medicines or foods, but are commonly (although not exclusively) biologically based products,[15] which may have some effect in treating, preventing or diagnosing illness, disease or symptoms, or promoting health and wellbeing;[16] whether that effect is real, or merely a manifestation of the placebo effect. These products often lack scientific evidence as to one or more of their safety, quality or efficacy.[17] They may be categorised as CAM products by: user-identification as a CAM product,[18] their inability or lack of desire to meet the scientific and legal requirements for recognition and regulation as a medicine, or third party identification as CAM products due to their failure to meet common standards or usual definitions of foods, conventional medicines, or any other broad category of product for direct human use.

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[12] World Health Organization *General Guidelines on Methodologies on Research and Evaluation of Traditional Medicine* (WHO, online ed, Geneva, 2000).

[13] National Center for Complementary and Integrative Health "Complementary, Alternative, or Integrative Health: What's In a Name?" (June 2016) <https://nccih.nih.gov/health/integrative-health>.

[14] Kaan, above n 8, at 420, when discussing the ideas of Mertz on a definition; see M. Mertz "Complementary and alternative medicine: the challenges of ethical justification. A philosophical analysis and evaluation of ethical reasons for the offer, use and promotion of complementary and alternative medicine" (2007) 10(3) Medicine, Health Care and Philosophy 329.

[15] Lucinda E. Jesson and Stacey A. Tovino *Complementary and Alternative Medicine and the Law* (Carolina Academic Press, North Carolina, 2010), at 6-10.

[16] Ministerial Advisory Committee on Complementary and Alternative Health *Complementary and Alternative Health Care in New Zealand: Advice to the Minister of Health* (Wellington, June 2004), at 1.

[17] Ellena, above n 9, at 106-107.

[18] Ministerial Advisory Committee on Complementary and Alternative Health, above n 16, at 1.

As an aside, it is important to note that the frequent use of the term 'quality' throughout this thesis is not synonymous with 'efficacy', but rather is used in reference to CAM (or other) products which are well-made, do not contain unlisted ingredients, fillers, or foreign constituents, but do contain the listed ingredients on the label, in the amounts stated thereon.

This entire thesis could be spent arguing the nuances of that definition of CAM products, and while there are undoubtedly flaws therein, it serves the purpose of facilitating discussion around their regulation, with a broad and reasonably flexible definition.

1.2.2 Dietary supplements

In 1985, when the DSRs were first published, the CAM product industry was generally limited to products classified as 'dietary supplements'. As the Regulations define them, these are amino acids, edible substances, herbs, minerals, synthetic nutrients or vitamins which are intended to supplement a person's diet.[19] The reason for the identification and definition of DSs in this section is that at the time of writing, these are the primary type of CAM product regulated in NZ under the DSRs, and thus they arise frequently throughout this thesis.

1.2.3 Traditional medicine

Generally, traditional medicine (TM) products are considered within the scope of CAM products throughout this thesis, except where explicitly noted. Nevertheless, it is worth briefly outlining two prevalent forms of TM in NZ to appreciate the nuances of the largest, discrete field under the overarching umbrella of 'CAM products'.[20]

Rongoā or 'Rongoā Māori' is Māori Traditional Medicine. It is an holistic form of healthcare and comprises three primary elements: rakau rongoā, akin to herbal medicine, mirimiri, or massage, and karakia, which is prayer.[21] Additionally, the mana[22] or standing of the tohunga (usually the expert healer or priest) comprises a vital part of the healing process.[23] The herbal treatments involve both

[19] Dietary Supplements Regulations 1985, reg2A.
[20] The other major forms of TM in NZ are Traditional Chinese Medicine, and Ayurvedic medicine, although in the interests of brevity, these are not substantially considered within this thesis.
[21] Ministry of Health "Rongoā Māori: Traditional Māori healing" (18 December 2015) <www.health.govt.nz/>.
[22] The concept of 'mana' is widespread throughout Polynesian cultures, and while lacking a concrete definition, is generally considered to encompass the prestige, honour, aura and identity of both a society and a people. It can be both a positive and negative element, but is inextricably interwoven with an individual, tribe and society's sense of identity and consequent behaviour. See Chris Winitana "The Meaning of Mana" *New Zealand Geographic* (online ed, New Zealand, January-March 1990) for more on Mana.
[23] Te Papa "Māori medicine" (2017) <www.tepapa.govt.nz/>.

internal and external application of native plants for treatment of a variety of ailments, from respiratory and digestive problems, to broken bones and dermatological conditions.[24]

While homeopathy does not have the same history of traditional use as other TM, it nevertheless has an important standing as a TM in Europe and abroad.[25] Developed in the late 18th century by Samuel Hahnemann,[26] homeopathy is premised on two principles; *similia similibus curentur* or the law of similars which claims that like cures like,[27] and the idea of 'potentisation', that the more dilute a homeopathic solution is made through dilution and constant shaking, the stronger the homeopathic remedy becomes.[28] The 'like cures like' principle rationalises that the cause of a problem can also be the cure for that problem, where the substance is diluted and shaken multiple times.[29] This theory of 'potentisation' defies established laws of pharmacology, biochemistry, chemistry and physics.

1.3 The Problems with NZ's CAM Product Regulations

There are a host of minor issues surrounding CAM regulation in NZ currently, however, for the purposes of this thesis, these can be grouped into two major heads: the failure of current and proposed legislation to effectively regulate CAM products, and the widespread information deficit about the size and scope of the CAM product market in NZ.

The DSRs are over 30 years old, and critiques acknowledge they are at best ineffective,[30] and at worst, they amount to deregulation.[31] In the past 20 years, there have been a number of proposals for new CAM product regulation, but nothing has come to fruition. Nearly all these approaches have attempted to regulate with insufficient information of the market they aim to govern, ultimately prioritising stakeholder satisfaction over sound evidence-based measures around the safety, efficacy and quality of CAM products. As a result, this problem continues to grow, with the only means of

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[24] At 1.
[25] This can be seen in the UK, with allowance for therapeutic claims on homeopathic products providing they are used within the established homeopathic tradition; Medicines and Healthcare Products Regulatory Agency "Register a homeopathic medicine or remedy" (27 January 2017) <www.gov.uk>.
[26] Edzard Ernst, Max H. Pittler and Barbara Wider (eds) *The Desktop Guide to Complementary and Alternative Medicine: An evidence-based approach* (2nd ed, Elsevier, Exeter, 2006), at 326.
[27] Michael Weir *Law and Ethics in Complementary Medicine: A handbook for practitioners in Australia and New Zealand* (5th ed, Allen & Unwin, Sydney, 2016), at 222.
[28] Ernst, Pittler and Wider, above n 26, at 326.
[29] At 326.
[30] Ministry of Health, above n 3, at 2-6.
[31] Barbara von Tigerstrom "Globalisation, harmonisation and the regulation of therapeutic products: the Australian New Zealand Therapeutic Products Authority in global context" (2007) 13 Canterbury Law Review 287, at IV.

enforcement around CAM products being the use of alternative legislation like the Medicines Act 1981 (MA) or Fair Trading Act 1986 (FTA), which act as a stop-gap.

The lack of information on NZ's CAM product market is inseparable from the first issue. While many of the proposed measures have highlighted the need for more information on; the CAM market, usage of CAM products, perceptions around CAM products, and the safety, efficacy, and quality of CAM products, no major work has been done in this area. As such, proposals like the NHSPB are destined to fail before they are even enacted, due to this information deficit which will cause regulators to wander blind into a huge market, plagued with issues no proposal has foreseen.

1.4 The Aim of this Thesis

There are three aims to this research. The first is to analyse specific and more general legislation, and its role in regulating CAM products. The second aim is gain a more detailed knowledge of the scale and scope of the issues with CAM products, through empirical data which will begin to address the information deficit. Finally, on the basis of the research and findings in this thesis, the third aim will be to design and propose a new piece of legislation to provide the best solution for the regulation of CAM products in NZ.

The first and second aims will be achieved through three stages. To begin, this research will review surrounding legislation, with an especial focus on risk-based legislation as a potential model for future CAM product regulation. This leads into the second stage, which comprises an in-depth study of the flaws with the current CAM product regulations, and reasons for failure of the various proposals. With a sound appreciation for this background, the third stage analyses whether alternative legislation is effective as a means of enforcement, in addition to delving deeper into the scale of the problems in a quantitative capacity. Through the coalescence of the review, research, and studies, the third aim will be met in the ultimate proposal of a new Bill for CAM product regulation.

1.5 The Scope & Limitations of this Research

Any research which aims to not only design new legislation, but also proposes addressing a large information deficit, must limit its scope at some point. While tomes could be written on this subject, there are three key areas which this research intentionally put aside in the interests of greater depth on the issues raised herein.

A conversation on CAM product regulation in NZ is complemented by a discussion and comparison of other major international actors, and their systems for CAM product regulation, but such a discussion must await another medium.

This thesis is focused on the issue of consumer protection legislation and the way it interacts with CAM products, but there is a similar topic to be addressed in the way intellectual property and CAM products intersect, especially insofar as traditional medicine, traditional knowledge, and patent law is concerned.

Finally, the legislation proposed is a draft Bill. It was neither the intention, nor the desire of this research, to put forward wording of every clause of the Bill, but rather to propose key provisions which contain a sound strategy for the regulation of CAM products, and address the problems raised throughout this thesis.

1.6 An Overview of this Thesis

The stages discussed at 1.4 to achieving the aims of this research give an indication of the structure of this thesis. There are four parts to this thesis, with each chapter building upon the information and research of those that precede it.

Part I discusses specific legislation; namely the Food Act (FA) of 1981 and 2014, the MA, the DSRs, and the NHSPB. This review of surrounding legislation enables a study of risk-based legislation in Chapters 2 and 3, before considering CAM product regulations and proposals, and the problems surrounding them in Chapters 4 and 5. This Part finishes with a case study in Chapter 6 of a controversial CAM product, Miracle Mineral Solution, and attempts to apply the legislation to this issue.

Part II takes a broader perspective. Initially, it considers the FTA and the Consumer Guarantees Act 1993 (CGA) as they may apply to CAM products, and uses the case study from Chapter 6 to demonstrate the ability of alternative legislation to address such matters. It turns from this general legislation to the issue of the Treaty of Waitangi and the Wai 262 Report in Chapter 8, to briefly discuss their role within CAM product regulation.

Part III introduces the substantial empirical research conducted in the course of this thesis. Chapter 9 details the Pilot Study and its findings on CAM product usage and misleading packaging and labelling. This is built upon by the Representative Study in Chapter 10, which provides the best indication of CAM product usage in the general NZ population in more than 20 years, as well as studying the impact of packaging more specifically on consumer perceptions of CAM products. This is followed by Chapter 11, which returns to the FTA to determine whether this alternative legislation can also adequately handle a novel issue like misleading and deceptive packaging.

Finally, this thesis culminates with Part IV. Chapter 12 corrals the strategies, solutions, and practical measures raised throughout the thesis, and crystallises them into a single piece of legislation for the

regulation of CAM products in NZ. This Bill aims to provide a new hope and future for CAM product regulation, bringing it out of the metaphorical wilderness of 30 years of effective deregulation.

1.7 Appendices

There are five appendices to this thesis. Appendices 1 and 3 contain Human Ethics Committee Approval for the two surveys which were conducted, while appendices 2 and 4 contain those two surveys: 'Public Perceptions on Dietary Supplements: A Pilot Study', and 'Packaging of Complementary and Alternative Medicines in New Zealand: A Representative Survey'. Appendix 5 contains the complete draft of the Complementary and Alternative Medicinal Products Bill, to facilitate ease of reference during the reading of this thesis, and Chapter 12 in particular.

Part I: Specific Legislation

2 Food

2.1 Introduction

As a nation which derives over 10% of its gross domestic product from its internal food sector,[32] employs 20% of the work force in the food sector,[33] and exports in excess of $20 billion of food related products per annum,[34] food safety and the thorough regulation of NZ's food industry is crucial.

To appreciate the position of NZ food regulation in the 21st Century, it is vital to understand the history of food legislation in NZ. Of particular importance is the FA 1981, which provided an invaluable regulatory foundation for the ensuing three decades, and supported the development of legislation, like the DSRs, which regulate products on the outskirts of food legislation.

Upon this background, as well as substantial scientific research, the rigorous new FA 2014 was developed, which employs a risk-based approach bringing NZ's food legislation in line with the best in the world; a crucial improvement for a country so dependent on its food export industry. This ensured NZ could uphold its obligations to key trading partners, and maintain relevance within the structure of the Australia New Zealand Food Standards Code 2002 (ANZFSC).

2.2 A History of Food Legislation

Food regulation in NZ began in the early days of the colony, with the enactment of the Adulteration of Food Act 1866, followed by the more comprehensive Sale of Food and Drugs Act of 1907. This was eventually replaced by the Food and Drug Act 1969, which was separated into two pieces of legislation in 1981: the FA[35] and the MA.[36] These Acts show the changing priorities of the times, with the 1866 and 1907 Acts focusing on the purity of foods or ramifications for a lack thereof, while the 1969 and

[32] (22 July 2010) 665 NZPD 12615.
[33] (13 May 2014) 698 NZPD 17755.
[34] Statistics New Zealand "Infoshare: Exports Summary Data Key Statistics Table 7.04 - Value of principal exports (Annual)" (24 August 2016) <http://www.stats.govt.nz/infoshare/>.
[35] Food Act 1981.
[36] Medicines Act 1981.

1981 Acts display a paradigm shift towards increasingly rigorous consumer protection through regulation of sale, advertisements,[37] hygiene,[38] and food safety and standards.[39]

Introduced into Parliament at the same time as the Medicines Bill,[40] the Food Bill of 1980[41] was relatively uncontroversial. The new Food Bill sought to control the entire process of food regulation, from preparation, storage, packaging and sale, through to import, export, labelling and marketing of food products.[42]

One issue received significant discussion in the passage of the 1980 Food Bill. The Minister of Health, Hon George Gair MP, commented that the Bill intentionally allowed for cross-over of DSs, slimming foods, or other special purpose foods, between food and medicine regulations on the grounds that, "[o]ne man's food may conceivably be another man's medicine."[43] The particular classification of these products would ultimately rest on their presentation to the public and the manufacturer's claims.[44] While the Labour Opposition attempted to illustrate the incongruity of regulating vitamin and mineral products with either the food or medicines' legislation,[45] Mr Gair contended that the categorisation of such products obviously rested on the quantity of vitamin or mineral present in the product, easily determining whether a product was a food or a medicine in its present form.[46] Despite Labour's concerns, this issue was relegated to discussion under the second reading of the Medicines Bill, and the Food Bill otherwise enjoyed bi-partisan support, receiving Royal Assent late in 1981.

In 2010, the new Food Bill was finally brought before the House, having begun its slow journey in 2003 when a review of food safety legislation was conducted, followed by the drafting of a new bill.[47] This tome aimed to replace the FA 1981, as well as repeal or amend associated legislation and regulations, including the Food Hygiene Regulations 1974, the DSRs, the Agricultural Compounds and Veterinary

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[37] Food and Drug Act 1969, ss3 and 6-11.
[38] Food Act 1981, Part 1A.
[39] At Part 2A.
[40] Medicines Bill 1980 (157-1).
[41] Food Bill 1980 (158-1).
[42] (12 December 1980) 436 NZPD 5919; The Act was in essence the first piece of legislation to endeavour to encompass all food activities, alongside similarly outdated regulations like the Food Hygiene Regulations 1974.
[43] (26 August 1981) 440 NZPD 2982; in specific reference to the non-exclusive definition of both food and drug in the 1969 Act, and the same between food, medicine and related product in the Food and Medicine Bills.
[44] At 2982.
[45] At 2983.
[46] At 2984.
[47] (13 May 2014) 698 NZPD 17750. The domestic food review took approximately 3 years, following which the new Food Bill began to be drafted. With a change of government in 2008, the introduction of the Bill was somewhat delayed, with a number of Ministries being reorganised, including the Food Safety Authority; (22 July 2010) 665 NZPD 12617 and (13 May 2014) 698 NZPD 17751.

Medicines Act 1997, the Animal Products Act 1999, and the Wine Act 2003. In addition to updating penalties and enforcement measures to bring them into line with similar legislation and be commensurate with the offence,[48] the Bill introduced to NZ a novel method of regulating food safety; a risk based approach.[49]

Delayed slightly by the scare of botulism contamination of NZ whey protein in 2013,[50] this Food Bill also moved through Parliament with widespread support, except on two issues: apparently unchecked regulatory power, and country of origin labelling. The initial iteration of the Food Bill took a strong regulatory approach, inciting fear that over regulation would adversely affect small businesses and uniquely NZ fixtures like the Saturday morning fundraising sausage sizzle.[51] However, fears were allayed following the Bill's return from the Select Committee, with the requirement that the regulation of such activities be reasonable and proportionate to their risk.[52] The second issue dividing the House was that of compulsory country of origin labelling on food. There was no country of origin labelling provision in the Bill, which reflected NZ's stance in the ANZFSC where an exemption had been sought to similar provisions.[53] However, there was significant opposition support for the inclusion of country of origin labelling, with the impetus behind it being that it demonstrated to both NZ and global consumers where food was sourced NZ, and also followed international trends in identifying food sourced in part or in full from other countries. While this matter was discussed in the Select Committee, as well as proposed by two supplementary order papers,[54] these were narrowly defeated by National's majority, primarily due to the commercial implications of such labelling. Nevertheless, a new proposal for country of origin labelling was introduced into Parliament by the Green party in 2016,[55] which will require country of origin labelling on most single component foods.[56]

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[48] (22 July 2010) 665 NZPD 12616.
[49] See 2.4 and 3.5.
[50] Miriam Dean, Anne Astin and Tony Nowell *The WPC80 Incident: Causes and Responses* (Department of Internal Affairs, 24 November 2014), at 5; In mid-2013, a batch of Fonterra milk powder was found to be contaminated with a strain of *Clostridium* bacteria, part of the family of bacteria which produce botulinum toxin which is potentially fatal to adults, and even more highly toxic in infants. As a result, global recalls of the product, and all products of which it was an ingredient were orchestrated, causing a significant fallout for Fonterra and New Zealand. As it eventuated, the bacteria was not the botulinum producing strain, and no adverse effects were reported.
[51] (22 July 2010) 665 NZPD 12626-12627; Labour MPs, namely Dr Ashraf Choudhary MP, Hon Damien O'Connor MP, and David Shearer MP.
[52] (13 May 2014) 698 NZPD 17756.
[53] (13 May 2014) 698 NZPD 17752-17753.
[54] Supplementary Order Paper 2014 (440) Food Bill 2010 (160-3); Supplementary Order Paper 2014 (449) Food Bill 2014 (160-3).
[55] Consumers' Right to Know (Country of Origin of Food) Bill 2016 (231-1).
[56] At s4; "single component foods means food or food products, whether packaged or unpackaged, that contain only one vegetable, fruit, meat, seafood, nut, grain, seed, or oil, although these may also contain water, sugar

This aside, the Food Bill had multi-partisan support, passing into law on the 6 June 2014, with a staggered process of commencement, beginning in earnest on 1 March 2016.[57]

2.3 Definitions within the Food Act 2014

There are two major changes insofar as the core definitions within the FA are concerned from its earlier 1980s iteration.

Foremost is the expansive new definition given to 'food' in the new Act.[58] The 1981 Act merely stated in s2 that "food means anything that is used or represented for use as food or drink for human beings…",[59] and then went on to list three specific categories which came under that umbrella: ingredients or nutrients, anything mixed with food or drink, and chewing gum. The 2014 Act incorporated these three categories, and extended the definition to include seeds, plants, plant material, and live animals, where any of those items are intended for human consumption, allowing the Governor-General to declare additional items as foods where necessary.[60] Furthermore, s9 explicitly excludes a number of items from being foods,[61] including "…any substances used only as medicines (within the meaning of the Medicines Act 1981)…".[62] The changes in the new Act also extend to ingredients, which are not required to comply on their own with the requirements of the Act,[63] so long as the food in its final form does meet the Act's requirements.[64]

This new 'meaning of food' in s9 gives wide scope to food within the Act, largely relying on the exclusions in subs(c), and legislation like the MA or Misuse of Drugs Act 1975 (MoDA) to limit what can be classified as a food.[65] There is little in the Hansard or associated materials to explain this expanded definition, but for NZ First MP Richard Prosser's speech on the Bill during the Committee Stage, where he emphasised the logical nature of the s9 definition, importantly noting "…it is the letter of the law that determines the relative foodness or non-foodness [sic] of any particular substance."[66]

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or its substitutes, salt, or other ingredients used in preserving, colouring or flavouring." At the time of writing, the Bill had near unanimous support in Parliament, and was before the Primary Product Select Committee.

[57] Food Act 2014, s2.
[58] At s9.
[59] Food Act 1981, s2, 'food'.
[60] At ss9(1)(b)(i)-(iii) and (viii).
[61] At s9(1)(c).
[62] At s9(1)(c)(iii).
[63] At s9(2).
[64] At s9(4).
[65] See 3.3.1.
[66] (14 May 2014) 698 NZPD 17850-17851.

The Act also expands the concept of safety,[67] ensuring that food will not cause illness or injury. However, it elaborates further than the previous Act, including the requirement that the food must be fit for purpose (that is the food must be correctly labelled, in good condition, and not harmed, damaged, or perished in any way).[68] Pertinently, the Act then employs these ideals in s14, in addition to the same statement in the purpose section,[69] requiring any person "…who trades in food [to] ensure that it is safe and suitable." Given the juvenility of the Act, these principles are currently untested, but it is likely that they will inform regulatory and judicial decision making, akin to 'purpose' sections.

2.4 A Risk-based Approach to Food Regulation

Where the 1981 food legislation required management of hazards to reduce risk, the new FA assimilates this with a plethora of other factors to take a more integrative, risk-based approach to food safety.[70] Hazard-based approaches generally view any deleterious component or potential consequence arising from the food as a rationale for regulation,[71] consequently creating the system in NZ which focused to a greater degree on microbiological hazard in the form of the control of food premises, rather than the food itself.[72] In addition, the somewhat ad-hoc development of the 1981 legislation and surrounding regulations resulted in varying levels of enforcement across local councils, rendering the system neither uniform, nor egalitarian.[73]

In contrast to a hazard-based approach, a risk-analysis within the context of food safety usually involves identification of a particular foodborne hazard, and then consideration of the exposure level.[74]

$$Risk = Hazard \times Exposure$$

Equation 2.1: Risk Equation[75]

[67] Food Act 2014, s12(2).
[68] At s12(3)-(5).
[69] At s4(f).
[70] (22 July 2010) 665 NZPD 12615.
[71] Eirini Tsigarida "Risk-based Approaches to Food Safety (Abstract)" (11 May 2016) International Association for Food Protection's European Symposium on Food Safety <https://iafp.confex.com/iafp/euro16/webprogram/Paper12746.html>.
[72] (13 May 2014) 698 NZPD 17750.
[73] (27 May 2014) 699 NZPD 18341; (14 May 2014) 698 NZPD 17845 and 17868. One particular foible of the 1981 Act was that regional authorities had discretion in their interpretation of the legislation and regulations, resulting in a confusing and changeable system with regards to both food standards and fees between different areas.
[74] Tsigarida, above n 71.
[75] See discussion on risk at 3.5.

This approach subsequently enables regulation commensurate with the exposure to the hazard, which determines the risk. In practice, a risk-based approach involves three stages; hazard determination, risk management and risk communication.[76]

Over the past couple of decades, a number of countries, including the World Health Organisation, have been researching the potential for the development of risk-based regulatory systems, which can take account of both microbial and chemical hazards in food and their effects across a population.[77] As a part of the review into food safety in NZ, similar research was carried out from the early 2000s, exploring the best method for ranking risks of food.[78] Amongst matters like strategic planning and the efficient allocation of regulatory resources, a core tenet of risk assessment in food safety involves a risk-ranking system.[79] On the basis of a number of discussion and review documents,[80] a single metric for risk assessment was eventually settled on for NZ, which could apply uniformly to microbiological and chemical hazards.[81] This metric is Disability Adjusted Life Years (DALY), which was chosen in favour of the similar, but less informative Quality Adjusted Life Years.[82]

$$DALY = YLL + YLD$$

Equation 2.2: Disability Adjusted Life Years[83]

Where: *DALY = Disability Adjusted Life Years*

YLL = Years of Life Lost due to mortality

YLD = Years of Life lived with a Disability

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[76] Tsigarida, above n 71.

[77] Robert B. Wallace and Maria Oria (eds) *Enhancing Food Safety: The Role of the Food and Drug Administration* (The National Academies Press, Washington D.C., 2010); Arie H. Havelaar and others "WHO Initiative to Estimate the Global Burden of Foodborne Diseases" (2013) 381(Supplement 2) The Lancet S59; Julia Black "Risk Based Regulation" (OECD, 1 December 2008); Frédéric Forge *Food Safety: An overview of Canada's approach* (Science and Technology Division, online, Government of Canada Publications, 16 October 2002).

[78] Peter Cressey and Rob Lake *Ranking Food Safety Risks: A Discussion Document* (Institute of Environmental Science & Research Limited, June 2003); Peter Cressey and Rob Lake *Ranking Food Safety Risks: A Prototype Methodology* (Institute of Environmental Science & Research Limited, October 2004); Minister for Food Safety *Regulatory Impact Statement: Food Bill* (New Zealand Food Safety Authority, 2 October 2009).

[79] Wallace and Oria, above n 77, at 79.

[80] Cressey and Lake, above n 78.

[81] Rob Lake *Risk Ranking: Development of a Single Metric for Risk Ranking by the NZFSA* (Institute of Environmental Science & Research, December 2006); Ministry for Primary Industries "Risk ranking" <http://foodsafety.govt.nz/>.

[82] The distinction between the two is that DALY is a negative consideration, looking at the loss stemming from a loss of quality of life, whereas Quality Adjusted Life Years (QALY) is more of a positive consideration, looking at the additional quality of life derived from treatment for example; Lake, above n 81. An equivalent formula for QALY to that seen for DALY at Equation 2.2 would look something like: $QALY = YLS \times U$, where YLS = Year or life lived in a state, and U = Utility value of that particular state or situation.

[83] Robin J. Lake and others "Risk Ranking for Foodborne Microbial Hazards in New Zealand: Burden of Disease Estimates" (2010) 30(5) Risk Analysis 743 at 743.

This formula takes account of the years of life lost due to mortality (YLL), and the years of life lived with a disability (YLD), which is weighted for the severity of the disability.[84] This metric will commonly be informed by the cost of the illness, which considers the monetary impact for the affected individual.[85] Through analysis of the statistical data on the effects of many pathogens, it is then possible to extrapolate a ranking in order to assess their relative risk. Nevertheless, such a system so inherently linked to numerical values suffers from the lack of reliable longitudinal data showing additive effects of chemicals in food products.[86] Summarily, risk is managed by minimising exposure to hazards.

With the strong foundation provided by an extensive, and generally workable, risk assessment method, it was possible to build the new FA measures to manage these risks. Under the FA, there are three broad classes for food sectors[87] based on risk.[88] The highest risk food sectors[89] are outlined in Schedule 1 of the Act, and are required to have food control plans in place which heavily regulate their operation.[90] In contrast, the lowest risk food sectors[91] as classified in Schedule 3 are not required to have any food control plan in place, nor operate under part of the national programme for food safety, due to the fact they pose negligible risk to public health.[92] The middle risk category[93] is subdivided into three further risk levels. These risk levels correspond to the particular national programme under which the food sectors must operate, dependent on the degree of risk they present.[94] As the name suggests, national programmes are generic systems which seek to control, mitigate and manage the risks presented by the particular food sectors which fall within each programmes' ambit.[95] This is a lower regulatory burden upon food sectors than the requirement to create a food control plan which

[84] At 743.
[85] At 744.
[86] Lake, above n 81, at 1.
[87] Food Act 2014, s8 'food sector'; "food sector means a group of 2 or more food businesses".
[88] At s20(2)(a).
[89] For example, retail food manufacturers like bakeries, dairy product manufacturers and meat product manufacturers; at Schedule 1, Part 3.
[90] At s21(3)(a).
[91] For example, once a year food trading, direct to consumer horticultural producers; at Schedule 3, Part 3.
[92] At s21(3)(c).
[93] For example, manufacturers of food additives, vitamins, minerals or other nutrients to be added to food; at National Programme Level 3, Schedule 2, Part 3. Manufacturers of confectionary or processors of nuts or seeds; at National Programme Level 2, Schedule 2, Part 4. Extractors and packers of honey; at National Programme Level 1, Schedule 2, Part 5.
[94] At s20(2)(c) and s21(3)(b).
[95] At s74; Ministry for Primary Industries "National programmes" (8 September 2016) <https://www.mpi.govt.nz>.

must be targeted to the individual food business.[96] At the time of writing, there have been no cases surrounding the national programmes or classification of food sectors.

Risk communication is perhaps the least studied component of food safety risk-based programmes, but remains vital for educating consumers about the processes in place, and minimising exposure through targeted information. While the Ministry of Primary Industries claims that communication occurs throughout the whole risk-based programme,[97] the reality is somewhat more limited, whereby warnings after the fact are one of the more common methods of risk communication, alongside limited guidelines on domestic food preparation and the components of food.[98] It is well recognised across the literature that risk communication is a commonly deficient, but vitally important, part of any risk management process, to ensure consumer involvement and participation in the minimisation and control of risks.[99]

2.5 The Relationship between the Food Act 2014 and other Legislation, Codes and Regulations

Where the 1981 FA blurred the lines between foods and medicines; an issue exemplified in the confusing and unworkable DSRs,[100] the new FA looks to foster increasing clarity between foods, medicines, DSs and other CAM products, an issue which will be expanded upon in subsequent chapters.[101] In order to carry out its purpose and aims of ensuring safe and suitable food, the FA must co-exist with a series of other legislation and regulations. These range from legislation and treaties concerning the relationship of the NZ food system with Australia's,[102] through to the relationship with more general Acts and regulations that govern the daily operation of the food and beverage sector in NZ.

2.5.1 The Australia New Zealand Food Standards Code 2002

The journey to a joint food standards agreement with Australia began in 1983, with the Closer Economic Relations Trade Agreement.[103] This led to the creation of the Trans-Tasman Mutual

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[96] Food Act 2014, s36.
[97] Hilary Eade "Food Safety in New Zealand" (University of Otago Public Health Summer School, February 2015) <http://www.otago.ac.nz/wellington/otago615295.pdf>, at 12.
[98] Ministry for Primary Industries "Food safety for consumers" <https://www.mpi.govt.nz/>; Ministry for Primary Industries "What's in our food?" <https://www.mpi.govt.nz/>.
[99] Gerd Gigerenzer *Reckoning with Risk* (Penguin Books, London, 2003), at Chs.1-2; Paul Slovic *The Perception of Risk* (Earthscan Publications Ltd., London, 2000), at Chs.9 and 13.
[100] See 4.4.
[101] See 3.4 and 4.4.
[102] See 2.5.1.
[103] New Zealand Australia Closer Economic Relations - Trade Agreement, with Exchange of Letters [1983] NZTS 1 (1 January 1983).

Recognition Agreement (TTMRA),[104] and the Food Standards Treaty,[105] from which both the ANZFSC and the agency in charge of the Code, Food Standards Australia New Zealand (FSANZ), originated.

The TTMRA, through the empowering NZ Act,[106] applies to most goods and services between NZ and Australia, and to achieve its goals, the Act requires that all other legislation be read subject to the TTMRA.[107] The effect of this is that all food, except for a small number of high-risk foods,[108] is subject to the TTMRA.[109] The fact that the FA makes no reference to the TTMRA is irrelevant in light of its place as overarching legislation.[110] The presence of the ANZFSC means that the only effect of the TTMRA is upon the import and sale of Australian food-stuffs.

While theoretically a bilateral agency, FSANZ operates on the basis of the Australian Food Standards Australia New Zealand Act 1991.[111] The primary duty of FSANZ is the administration of the ANZFSC, which extends to drafting new food standards, and generally ensuring a safe, co-ordinated system of food safety between Australia and NZ.[112] FSANZ authority does not extend to enforcement of the Code, which remains the responsibility of the Ministry for Primary Industries[113] and local government in NZ.[114] The focus of the ANZFSC is setting standards for food contents, ensuring food safety, and putting in place labelling requirements for food.[115] Chapter One of the ANZFSC considers generally the food standards and labelling requirements, which apply to all foods, while Chapter Two looks at the food standards applicable to particular items.[116] The remainder of the ANZFSC, comprising Chapters Three and Four does not apply to NZ.[117] Additionally, it is important to note that the ANZFSC

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[104] The Trans-Tasman Mutual Recognition Agreement which was brought into force in NZ through the Trans-Tasman Mutual Recognition Act 1997, and aims to encourage an integrated trans-Tasman economy and foster closer economic ties and co-operation; Trans-Tasman Mutual Recognition Agreement 1998.
[105] Agreement between the Government of New Zealand and the Government of Australia establishing a System for the Development of Joint Food Standards [1996] NZTS 9 (1 January 1996).
[106] Trans-Tasman Mutual Recognition Act 1997.
[107] At s5.
[108] High-risk foods exempt from the TTMRA include beef, fish, dried coconut, peanuts, pistachios and seaweed; John Holah and Huub Lelieveld *Hygienic Design of Food Factories* (1st ed. ed, Woodhead Publishing, United Kingdom, 2011), at 128.
[109] Ministry for Primary Industries "Trans-Tasman Mutual Recognition Agreement (TTMRA)" (2016) <http://www.foodsafety.govt.nz/>.
[110] At 1.
[111] Food Standards Australia New Zealand Act 1991 (Cth).
[112] Food Standards Australia New Zealand "What we do and don't do" (August 2012) <http://www.foodstandards.gov.au/>.
[113] Formerly Ministry of Agriculture and Fisheries (MAF).
[114] Food Standards Australia New Zealand "Food Standards Australia New Zealand" (2015) <http://www.foodstandards.gov.au/>.
[115] New Zealand (Australia New Zealand Food Standards Code) Food Standards 2002.
[116] Food Standards Australia New Zealand "Food Standards Code" (1 March 2016) <http://www.foodstandards.gov.au/>.
[117] At 1.

does not regulate or provide standards for DSs or any therapeutic goods.[118] The FA gives effect to the NZ's obligations under the ANZFSC in ss397-402 FA. [119]

2.5.2 The Dietary Supplements Regulations 1985

A discussion of the legislation and regulations surrounding the FA in both its 1981 and 2014 iterations would be incomplete without at least noting the DSRs. As previously discussed, significant room was left in the 1981 FA for the Minister to make regulations; and one key area where this power was brought to bear was the DSRs, which came into force in 1987.[120] The DSRs govern the sale, export, and labelling of DSs, as well as listing some of the ingredients permitted in DSs. Despite a number of moves to repeal or substantially update this system, the DSRs remained in force for the duration of the 1981 FA's existence. Given the legislative delay and troubles encountered by the NHSPB,[121] the regulations were carried over into the 2014 FA, and remain in force at the time of writing.[122] A full discussion of the DSRs is in Chapter 4.

2.6 Advertising and Labelling

The FA does little to control or stipulate the content of food advertisements.[123] Section 238 FA sets out the variety of offences around advertising relating to food or food-related accessories, which can be largely grouped into three categories; advertisements which breach the requirements of the FA, advertisements which are misleading or deceptive, or advertisements which omit to include information required by the FA.[124]

There are two industry codes which set out guidelines for the advertising of food. Foremost is the Code for Advertising Food,[125] which concerns advertisements for food and beverages directed at people 14 years and older. The principle of this Code is that advertising should be conducted in a 'socially responsible' manner which 'does not mislead or deceive the consumer'.[126] Additionally, the

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[118] Ministry for Primary Industries "Food Standards Australia New Zealand (FSANZ)" (2016) <http://www.foodsafety.govt.nz/>
[119] Food Act 2014, s396.
[120] Dietary Supplements Regulations 1985, s1(3).
[121] Natural Health and Supplementary Products Bill 2011 (324-2).
[122] Food Act 2014, s413(3).
[123] Compare to the stringent criteria for advertising medicines; see 3.3.4.
[124] Food Act 2014 s238(2)
[125] Advertising Standards Authority *Advertising Codes of Practice 2014* (online ed, Advertising Standards Authority, 2014), at 35.
[126] Advertising Standards Authority "Code for Advertising Food" (2016) <http://www.asa.co.nz/>.

Children's Code for Advertising Food has a similar purpose, but recognises the susceptibility and receptivity of children under the age of 14 to advertising, and formulates the code accordingly.[127]

There are additional regulations regarding the advertising of supplemented foods, especially insofar as health claims may be made for such products, but this will be discussed when considering DSs, given the relationship of these products, at Chapter 4. Likewise, the FTA and CGA have roles in ensuring the advertising and statements on the packaging of food and beverages are not misleading or deceiving the consumer by falsely representing the food to be something it is not. These Acts will be discussed further in Chapter 7 in the context of CAM products.

2.7 Conclusion

Substantial work was done to create the 2014 FA and bring the legislation into the 21st Century with a well-researched scientific approach, which built upon the foundations of the 1981 Act, but substantially improved food regulation through the adoption of a risk-based approach. This brings the FA into line with legislation like the MA, which was one of the earliest instances of a risk-based strategy for regulation of products in NZ.

Through this risk-based approach, in addition to a detailed and well considered stance on what amounts to 'food' within the Act, the FA sets the benchmark for future NZ legislation regulating food, medicines, therapeutic goods and CAM products, independently, and in conjunction with international agreements and trade-relationships.

[127] Authority, above n 125, at 21.

3 Medicine

Herbal medicine is an area where we find some of the best evidence in all of alternative medicine. Some herbal extracts contain pharmacologically active compounds that obviously can have health effects – both positive and negative. This means that some herbal supplements are effective but the question is, which? In the absence of regulatory oversight to enforce standards for purity, concentration and dosage limits, herbal medicines may very definitely cause harm.[128]

3.1 Introduction

The MA 1981 adopts a sound, risk-based approach to the regulation of medicines, which has remained relatively unchanged for more than 35 years. When enacted, this was a novel form of regulation, however, through clear and effective regulations, and the governance and implementation by competent and clearly-defined regulatory bodies, the MA has remained relevant into the 21st Century. Nevertheless, with new legislation around food and food sectors, and imminent legislation surrounding CAM products, there is a view towards an updated approach to medicines' regulation in the Therapeutic Products Bill.

This Chapter considers key definitions in the MA, especially where they impact upon the regulation or enforcement actions against CAM products, like the notorious 'therapeutic purpose'. It also builds upon two issues introduced in Chapter 2; the relationship between medicines and foods, and the concept of risk in legislation, concluding by reviewing how the MA interacts with other legislation. Before delving into the effects and nuances of the MA with a view to CAM products, it is first necessary to appreciate the impetus for the development of the MA.

3.2 Medicines' Legislation

The 1960s saw one of the greatest medical tragedies of the 20th Century when an unknown side effect of thalidomide for pregnant women became apparent. Intended as a sedative for insomnia and anxiety, thalidomide was commonly prescribed for the off-label use of alleviation of morning sickness during pregnancy. Thalidomide was used for a number of years before it was identified as a teratogen, [129] affecting approximately 24,000 babies and resulting in 123,000 still-births or miscarriages.[130] A consequence of this tragedy was an increased movement worldwide, including in

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[128] Edzard Ernst *A Scientist in Wonderland: A Memoir of Searching for Truth and Finding Trouble* (Imprint Academic, United Kingdom, 2015), Addendum.

[129] A teratogen is; "an agent or factor which causes malformation of an embryo" *Oxford Dictionaries*, 2017, online ed)'teratogen'

[130] Thalidomide Society "About Thalidomide" (2017) <www.thalidomidesociety.org>.

NZ, to introduce more thorough, safety conscious medicines' legislation.[131] In conjunction with this, more extensive toxicity testing was implemented for new medicines to avoid missing key markers like that of the animal embryo resorptions which occurred for thalidomide during testing, masking its toxicity.[132]

Prior to 1980, NZ's medicine regulatory environment was controlled by a number of pieces of legislation; the Food and Drug Act 1969, the Restricted Drugs Act 1960, the MoDA, and the Poisons Act 1960. In December 1980, the Minister of Health introduced the Medicines Bill into Parliament to consolidate the control of medicinal products into a single Act, and to cohere with the Food Bill of 1980.[133] The Medicines Bill passed into law late in 1981. A few years later, the extensive Medicines Regulations 1984 came into force, providing much of the practicalities to the MA 1981 and enabling its commencement on 1 August 1984.[134] In a testament to the MA, it lasted with remarkably few amendments or calls for repeal into the 21st Century.

In the late 1990s, there began an almost 20-year conversation with Australia on creating a joint regulatory scheme; the Australia New Zealand Therapeutic Products Agency (ANZTPA). As a part of this plan, NZ's medicine legislation would require amendment, becoming more akin to Australia's Therapeutic Goods Administration (TGA), but with a bilateral regulator. However, the combination of a lack of public enthusiasm, and varying levels of commitment from successive governments saw this scheme fatally falter in November 2014.[135]

At this time, the Minister of Health, Hon Dr Jonathan Coleman announced that work would begin on a comprehensive new regulatory scheme including medicines, medical devices and cell and tissue treatments to replace the MA.[136] With an all-encompassing approach, this Therapeutic Products Bill aimed to establish a strong regulatory stance that maintains relevance through empowering a new

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[131] The Food and Drug Act 1969 and Medicines Act 1981 were catalysed, at least in part, by the thalidomide crisis, as seen in their novel response to safety and quality concerns with respect to medicines in contrast to the earlier Sale of Food and Drugs Act 1907. Many other countries updated or overhauled their medicines legislation in the wake of this tragedy, including the Drug Efficacy Amendment (Kefauver Harris Amendment) Ch 87-781, 76 Stat. 780 (1962) (USA) in the United States, and the Medicines Act 1968 (UK) in the United Kingdom.

[132] Steve K. Teo and others "Effects of thalidomide on reproductive function and early embryonic development in male and female New Zealand white rabbits" 2004 71(1) Birth defects research. Part B. Developmental and reproductive toxicology 1, at 15; no teratogenic effects were seen in the animals used for toxicity testing, as it later turned out, due to resorption of effected embryos. Consequently, the first sign of the teratogenic effects were in humans, where embryo resorptions do not occur.

[133] (12 December 1980) 436 NZPD 5918.

[134] Medicines Act Commencement Order 1984.

[135] Ministry of Health *Therapeutic Products Regulation Paper 1: Context and Overview* (November 2015) at 3; see further discussion at 5.3.1.

[136] At 3.

government department with extensive regulatory and decision making powers to control medicines and other aforementioned therapeutic products.[137] In this way, the Therapeutic Products Bill would complement the new FA, to bring the legislative triumvirate of food, medicine and CAM products into the 21st Century. At the time of writing, an exposure draft of the Bill allowing for public and stakeholder consultation was due for release at the end of 2017.[138]

3.2.1 Medicines Act 1981 & Medicines Regulations 1984

While the Medicines Bill was primarily intended to consolidate the earlier legislation, it also introduced a couple of important changes, for example including natural remedies in its purview, and increasing the authority of the responsible minister by extending their ability to make regulations. As a result of these new provisions, the progress of the Bill through Parliament in 1980 was a somewhat rocky journey.

As stated in the Parliamentary debate on the Bill, "There is a movement towards natural remedies… [and] alternative health care is attracting a growing number of followers".[139] The Labour opposition cast the issue as being about freedom of choice, and the ability to choose one's health remedies with seemingly little restriction.[140] The provisions in the Medicines Bill in relation to natural remedies were significantly reworked at the committee stages, eventually compromising by reducing any restrictions on natural remedies and classifying them as foods within the FA, so long as they did not make any TCs.[141] Nevertheless, 'Herbal Remedy' is still defined in the Act as a medicine,[142] although this appears to have had little effect since the Bill's passing.

The Act also allowed for the drafting of extensive regulations, and the Medicines Regulations 1984 (MRs)[143] were empowered by the Governor-General under s105 MA in 1984. In concert with s3(3) MA, reg3 MRs introduces the permissive 'white list'[144] approach for categorising medicines into either

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[137] At 1-2; Ministry of Health *Therapeutic Products Regulation Paper 2: Proposals for a Therapeutic Products Bill* (November 2015) at 10-14.
[138] Ministry of Health "Therapeutic products regulatory regime" (14 June 2017) <www.health.govt.nz/>; despite the change of government, the Ministry of Health appears to still be aiming for an exposure draft to be released prior to the end of 2017.
[139] (9 July 1981) 438 NZPD 1400.
[140] At 1400; this matter has once again been at the forefront of public attention as the NHSPB progressed through Parliament. See further at Chapter 5.
[141] (26 August 1981) 440 NZPD at 2985.
[142] Medicines Act 1981, s2.
[143] Medicines Regulations 1984
[144] This model of regulation known only permits products named on the list to be used, either alone or in combination, in the manufacture of medicines or CAM products. It is commonly known as a 'white list'.

prescription medicines,[145] restricted medicines,[146] or pharmacy-only medicines,[147] with the latter two being accompanied by dose restrictions. Despite the MRs not controlling general sale medicines, they provide an otherwise thorough basis for the administrative operation of the MA; simultaneously heralding an uncommon vesting of power in subordinate legislation.[148]

3.2.2 Regulatory bodies under the Medicines Act 1981

There are three primary bodies which were created under the MA. These exist in a pseudo-hierarchical structure, whereby the NZ Medicines and Medical Devices Safety Authority (Medsafe), sits at the head, followed by the Pharmaceutical Management Agency (PHARMAC). Finally, Medicines Control as a part of the Ministry of Health (MoH) is at the bottom of the ladder.

Medsafe is a business unit of the MoH, whose responsibility is generally to administer the MA and MRs.[149] Medsafe operates on a platform of dual accountability, where it is naturally responsible to the MoH, but additionally is responsible to the pharmaceutical industry, which partially funds Medsafe through fees paid for its services and related activities.[150] One of the most important responsibilities of Medsafe is the assessment of new medicines through a multi-faceted process, which determines whether they may be marketed in NZ.[151] More generally, Medsafe regulates any product covered by the MA through granting approval where they meet the requisite standards, and continuing post-market monitoring if the products gain marketing approval.[152]

A key element of the regulatory process which remains outside Medsafe's purview is that of funding medicines. Determining which medicines to fund and distributing this funding is the responsibility of PHARMAC. PHARMAC is a government agency which receives its funding from both national and local government through the District Health Boards.[153] The rationale behind the concept of a nationally funded pharmaceutical program is in keeping with NZ's approach to public healthcare, with PHARMAC existing to increase NZ's purchasing power with regards to pharmaceuticals by tendering for medicines to reduce costs.[154] This role of funding pharmaceuticals extends to contract negotiation and funding of medical devices in hospitals, as well as campaigns for responsible use of medicines and

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[145] At Sch.1, Pt.1.
[146] At Sch.1, Pt.2.
[147] At Sch.1, Pt.3.
[148] Ministry of Health, above n 135, at 3.
[149] Medsafe "About Medsafe" (29 September 2015) <http://www.medsafe.govt.nz/>.
[150] At 1.
[151] See discussion at 3.3.1 on the assessment of new medicines.
[152] At 1.
[153] PHARMAC "Introduction to PHARMAC" (11 October 2016) <http://www.pharmac.govt.nz/>
[154] PHARMAC "PHARMAC history" (11 October 2016) <http://www.pharmac.govt.nz/>

administration of the Pharmaceutical Schedule, which contains information on all the medicines and therapeutic products which district health boards fund.[155]

Finally, Medicines Control operates within the MoH as a regulatory team; that is, as an enforcement taskforce for the control of medicines and drugs within NZ.[156] While Medicines Control also facilitates the administration of the MA and MRs, the fact that they primarily monitor compliance with the legislation, enforcing decisions made by Medsafe, and issuing licences, except for those which permit manufacture and packaging of medicines (something within Medsafe's purview) is evidence to the fact that they are merely an enforcement subsidiary, rather than a corollary to Medsafe.[157]

3.2.3 The emerging need for new regulation

Increasingly, the MA, and its associated regulations are in need of reform due to their age and reactive, rather than proactive approach to regulation of medicines, medical devices and related products. Furthermore, the enforcement provisions within the Act[158] are uncertain, and insufficient to act as a suitable deterrent.[159] This results in enforcement actions being taken under alternative legislation like the FA[160] and the FTA[161] instead, where enforcement is straight-forward and yields penalties commensurate with the offence.[162] The need for a modern, functional medicines legislation, which addresses such issues and allows thorough control of therapeutic products within NZ has been driving the desire for a new form of regulation over the past decade.

3.2.4 Therapeutic Products Bill

Rising from the ruins of the ANZTPA, the development of a Therapeutic Products Bill was first voiced at the end of 2014.[163] A year later, the Minister of Health produced two papers on the context and

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[155] PHARMAC "Inside the Pharmaceutical Schedule" (18 October 2016) <http://www.pharmac.govt.nz/>
[156] Ministry of Health "Medicines control" (3 August 2016) <http://www.health.govt.nz/>
[157] At 1.
[158] Medicines Act 1981, Part 5: Enforcement.
[159] Ministry of Health, above n 137, at 9-10; Ministry of Health *Regulatory Impact Statement: Therapeutic Products Regulation* (November 2015) at 37-41.
[160] Food Act 2014 and Food Act 1981; see for example in *Honey New Zealand (International) Limited v Director General of the Ministry for Primary Industries* [2016] NZCA 141 where an appeal against a decision on a potential health claim or therapeutic claim was taken under the ANZFSC. While the original decision was overturned on appeal, it demonstrates a proclivity towards any legislation other than the MA for enforcing principles enshrined in the MA.
[161] Fair Trading Act 1986; see for example in *Commerce Commission v John Graham Godwin and Anor* DC Tauranga CRI-2007-070-0007795, 14 January 2009, where the defendants pleaded guilty to 19 charges under the FTA regarding claims for a bird flu remedy, a remedy for herpes, an anti-terrorist kit, and a remedy for SARS. While the business they were conducting operated on the pretences of homeopathy, the issue in the case with regard to their remedies was the false therapeutic claims which were being made. Nevertheless, the CC took the action forward under the FTA rather than the MA, resulting in a judgment of costs of $10,000 total.
[162] B Robertson "Editorial: Ban or Regulate" [2014] NZLJ 121 at 121.
[163] Ministry of Health, above n 135, at 3.

overview,[164] and proposals[165] for the Bill, accompanied by a Regulatory Impact Statement from the MoH.[166] Six months later, the Minister released another paper recounting further policy approvals[167] for the new Bill, alongside a second Regulatory Impact Statement.[168] These papers envisaged an exposure draft[169] facilitating stakeholder consultation to be released during 2016,[170] followed by the Bill being introduced to Parliament late in 2016,[171] with a view to the quick passage of this Bill to law in 2017.[172] However, at the time of writing, the release of the exposure draft had been delayed until the end of 2017 "…due to the number and complexity of the issues to be worked through."[173]

The papers on the new Bill identify several key areas where changes from the current MA and MRs will arise. The new Bill will take a much more general focus on therapeutic products, including, but not limited to, medicines, blood and blood products, medical devices, cell and tissue therapies, and hybrids of these categories.[174] Through generalised and flexible primary legislation, the Bill will endeavour to future-proof itself to incorporate any unforeseen new therapeutic products,[175] operating largely through subordinate legislation and the regulatory departments which the totality of the legislation will empower.[176] Given the breadth of regulation proposed by the papers, there may be significantly greater interface between the Therapeutic Products Bill, and other legislation including;[177] the Hazardous Substances and New Organisms Act 1996, the FA 2014, the Psychoactive Substances Act 2013, the MoDA, the Human Tissue Act 2008, the Health Practitioners Competence Assurance Act 2003, and the NZ Public Health and Disability Act 2000. Were this increased interface to occur, it would likely be a result of legislation which is more flexible and designed to allow recent developments and research in matters surrounding medicines, medical devices, human tissue and other therapeutic products to affect how they are controlled between the various acts.

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[164] At 3.
[165] Ministry of Health, above n 137.
[166] Ministry of Health, above n 159.
[167] Ministry of Health *Therapeutic Products Regulation: further policy approvals* (March 2016).
[168] Ministry of Health *Regulatory Impact Statement: Therapeutic Products Regulation - Analysis of specific issues and options* (March 2016).
[169] An exposure draft is a fairly new addition to the legislative process, which envisages the release of a draft of a bill to the public and stakeholders prior to the bill being introduced to Parliament. The purpose of such a draft is to gain input and consultation from interested parties to rectify practical problems or clarify technical details in the legislation. The Treasury "Turning Policy into Legislation" (28 July 2016) <http://www.treasury.govt.nz/>.
[170] Ministry of Health, above n 167, at 13.
[171] At 1.
[172] Ministry of Health, above n 135, at 1.
[173] Ministry of Health, above n 138.
[174] At 2.
[175] At 3.
[176] Ministry of Health, above n 137, at 10-12; Ministry of Health, above n 167, at 10-11.
[177] At 2-3.

3.3 Definitions and the Impact of the Medicines Act 1981

3.3.1 The definition of medicines

There are two main requirements within the MA for a substance to be classified as a medicine. The particular substance must be primarily for use in humans for a therapeutic purpose,[178] and should achieve this therapeutic purpose, or be likely to do so "…by pharmacological, immunological or metabolic means."[179] The concept of therapeutic purpose in the MA is discussed below in detail at 3.3.2. Section 3(1) MA goes on to exclude items like medical devices[180] and food[181] from the purview of the definition of 'medicine', leaving a fairly narrow type of product which meets this classification.

The Act then further defines particular types of medicines, which may be grouped into two broad categories: new medicines and approved medicines.

As the term suggests, a new medicine is one which has either not been generally available in NZ in the last five years,[182] or is a product which seeks to alter its previously approved classification or chemical composition.[183] An assessment of new medicines considers the safety, efficacy, and quality standards associated with the application for approval of the new or changed medicine, and this information is used to inform the Minister of Health on whether the medicine has a suitable risk-benefit basis for approval.[184] In carrying out this process, Medsafe evaluates the data and information provided by the sponsor[185] against the international standards of similar drug regulatory agencies like the USA Food and Drug Administration, the European Medicines Agency, Health Canada, and the International Council for Harmonisation.[186] While the data requirements for each new medicine application will differ slightly, this information must demonstrate key safety, quality, and good manufacturing practices (GMP).[187] Such evidence will commonly take the form of detailed chemical analyses of active and non-active ingredients, the chemical and mechanical process for producing the medicine,

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[178] Medicines Act 1981, s3(1)(a)(i).
[179] At s3(1)(a)(ii).
[180] At s3(1)(c)(i).
[181] At s3(1)(c)(ii).
[182] At s3(3)(a)(ii).
[183] At s3(3)(c) and s3(3)(d).
[184] Medsafe *Guideline on Regulation of Therapeutic Products in New Zealand, Part 2: Obtaining approval for new and changed medicines and related products* (March 2016) at 5.
[185] Medsafe "Regulatory Guidance" (19 June 2015) <http://www.medsafe.govt.nz/> defines 'Sponsor' as; "…the person or company legally responsible for placing the product on the market in New Zealand. As sponsor, you must have a physical address in New Zealand." Section 21(1)(b) MA 1981 further specifies the entities who may be sponsors.
[186] Medsafe "Medsafe's Evaluation and Approval Process" (4 July 2013) <http://www.medsafe.govt.nz/>
[187] At 1.

information on the quality tests and controls in place, and the results from extensive animal and human clinical studies.[188]

Within the group of approved medicines, there are four classes into which medicines may be further categorised: prescription medicines, restricted medicines, pharmacy-only medicines and general sale medicines. This categorisation is instigated by the sponsor, who notes in their new drug application where they envisage their drug being classified. While in principle higher risk drugs will require substantially more information for the new drug application, most sponsors in practice include all this information regardless of the classification they are seeking. The final decision on classification of the new medicine is made by the regulator, although it is usually the same as that identified by the sponsor. After approval has been granted and the medicine has been marketed for a period of time, the sponsor may make a changed medicine application to apply for a lower classification if post-marketing monitoring demonstrates low risks. Occasionally, further research will uncover additional risks from a product which has received approval to be marketed over-the-counter, and in these cases, the regulator or drug company may reclassify the drug in a higher risk category[189] or remove it from the market altogether.[190] Except for general sale medicines, each medicine which receives approval is then listed in Schedule 1 of the MRs, or on the Medsafe Classification Database[191] under its appropriate category. The only mention of general sale medicines in the MA is to note the ability of the Director-General to publish a list of these medicines which do not come within the other three categories.[192] Instead, the full record of general sale medicines is available on the Medsafe Classification Database,[193] generally accompanied by dose conditions, as are restricted medicines[194] and pharmacy only medicines.[195]

[188] At 1.
[189] As was the case with the reclassification of Pseudoephedrine in New Zealand; see Medsafe Ephedrine and Pseudoephedrine to become Controlled Drugs, and Ministry of Health *Advice to the Expert Advisory Committee on Drugs on: Pseudoephedrine* (June 2009).
[190] See for example the case of Phenylpropanolamine increasing the risk of haemorrhagic stroke in women and its consequent removal from the market by the FDA - Food and Drug Administration FDA Letter to Manufacturers of Drug Products Containing Phenylpropanolamine (PPA) dated 11/03/2000 and Food and Drug Administration "FDA Issues Public Health Warning on Phenylpropanolamine" (press release, 6 November 2000).
[191] Medsafe "Database of Medicine Classifications" (16 August 2013) <http://www.medsafe.govt.nz/>
[192] Medicines Act 1981, s99.
[193] Medsafe, above n 191.
[194] Medicines Regulations 1984, Sch.1, Pt.2.
[195] At Sch.1, Pt.3.

3.3.2 Therapeutic purpose

One of the key measures in place to distinguish foods and associated products from therapeutic products is that medicines,[196] medical devices[197] and related products[198] have a therapeutic purpose and consequently, may make TCs.[199] Section 4 MA defines therapeutic purpose in broad terms, meaning any preventative, diagnostic, or curative measure for a malady, injury,[200] pregnancy[201] or conception,[202] as well as any modification of a physiological process,[203] or part of the human anatomy.[204] Therapeutic claims exclusively describe the treatment of a medical condition (the therapeutic purpose) for which the medicine was granted approval.[205] Due to the MA's monopoly on TCs, any other product making such a claim is holding itself out as a medicine or related product when this is not the case, thus breaching s20(2) MA as well as engaging in misleading or deceptive conduct or representations contrary to the FTA.

3.3.3 Related products

'Related products' is a broad term used in the MA to encompass any cosmetic, dentifrice, or food which makes a TC.[206] In the event one of those three products makes a TC and becomes a related product, certain sections of the MA apply to the products in the same way those sections apply to medicines.[207] Consequently, s20 prohibits the sale, distribution, or advertisement of related products where they do not have approval from the Minister. These provisions around related products arise fairly regularly in relation to CAM products as seen throughout this thesis, as this is one of the avenues for prosecuting a company who makes TCs on their CAM products.[208]

3.3.4 Medicine marketing and advertising

A benefit of obtaining approval as a medicine is the ability to market the product with TCs. This informs the consumer exactly what the product will do, and theoretically differentiates medicines from arguably less effective, less regulated CAM products. Aside from the benefits to the supplier,

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[196] Medicines Act 1981, s3(1)(a)(i).
[197] At s3A(a)(i).
[198] At s94(1).
[199] Compare the NZ definition of 'therapeutic purpose' in s4 MA with the Australian equivalent in Therapeutic Goods Act 1989 (Cth), s3(1) of 'therapeutic use'.
[200] Medicines Act 1981, at s4(a).
[201] At s4(e).
[202] At s4(d).
[203] At s4(b).
[204] At s4(f).
[205] Advertising Standards Authority "Therapeutic and Health Advertising Code" (2016) <http://www.asa.co.nz/>
[206] Medicines Act 1981, s94(1).
[207] At s96.
[208] See 4.4.2 on the impact of therapeutic claims.

there is a public benefit in being able to select medicines best suited to the affliction. As such, the MRs requires all medicines except for prescription medicines to display a statement of purpose on their label indicating the medicine's intended use.[209] A medicine's intended use is that use for which the medicine received marketing approval.

Similarly, advertisements for all medicines must contain a statement of the therapeutic purpose for which the medicine received consent.[210] However, this regulation must be read in light of the restrictions on advertisements in the MA.[211] Section 58(1)(a) and (b) prevent advertisements that claim treatment or cure of conditions specified in Parts 1 and 2 of Schedule 1 MA. The purpose of such a restriction would appear to be consumer protection, given the general lack of a remedy for most of the scheduled conditions. Further credence is added to this view by s58(3), which goes on to note that truth is a good defence to a breach of subs(a) and (b). Thus, verifiable treatment or cure of the scheduled conditions will obviate any prosecution under this section.

In addition to the restrictions on advertising imposed by the legislation, there are a range of guidelines and services governing the advertising of therapeutic purpose. The advertising industry recognises the social responsibility which comes with the benefits of making TCs, and therefore has developed extensive guidelines[212] and vetting for TCs.[213] While essentially a collation of material from the relevant legislation, the Advertising Standards Authority Code condenses and simplifies this to set out the responsibilities of advertisers, and the manner in which advertisements should be executed.[214] Along similar lines, the Association of New Zealand Advertisers has developed a thorough set of guidelines and checklists regarding medicines advertising,[215] as well as a pre-vetting service[216] which endeavours to aid advertisers in complying with therapeutic advertising regulations, as well as preventing TCs for unauthorised products; a pervasive issue with regards to CAM products, which will be considered further at Chapter 4. Additionally, the FTA and CGA both contain checks on misleading or deceptive advertising practices, or remedies where the goods do not match their description in an advertisement. This legislation and its value in handling false representations especially is discussed in more detail in relation to CAM products at Chapter 7.

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[209] Medicines Regulations 1984, reg13(j).
[210] At reg8.
[211] Medicines Act 1981, ss57-58.
[212] Advertising Standards Authority, above n 205.
[213] Association of New Zealand Advertisers "TAPS Prevetting System" (2016) <http://www.anza.co.nz/>
[214] Advertising Standards Authority, above n 205.
[215] Association of New Zealand Advertisers "Medicines Guidelines" (2016) <http://www.anza.co.nz/>
[216] Association of New Zealand Advertisers, above n 213.

3.4 The relationship between medicine and food

The relationship between medicine and food regulation is a complex one. While both pieces of primary legislation are intended to operate independently with little overlap, the relationship which exists in practise is one which resides in the grey areas between the definitions proffered in the legislation.

3.4.1 'Food' in the Medicines Act 1981

In addition to defining a medicine in s3, the MA provides a list of items which do not qualify as medicines for the purposes of the Act. Included in this list, is "any food within the meaning of s2 of the Food Act 1981…"[217] Aside from the fact that this has not been updated to refer to the new FA in the 7 March 2017 MA reprint, the effect of this section still elicits a blanket ban on foods and ingredients[218] from being a medicine. It is important to note two factors which permeate this issue. While little commentary or case law is available on the interpretation of s3 MA, it is likely that the aim of the section is to define a medicine as something intended primarily for a therapeutic purpose in humans,[219] which seeks to avoid absurdity through the exclusion of some other substances.[220] Furthermore, as evidenced by the lack of update to bring the MA in line with current associated legislation, it is likely that the MA is now in a period of decline as new legislation is drafted to overhaul the medicines regulatory system, and therefore in effect, a strict interpretation of the definition in s3 is redundant.[221]

3.4.2 'Medicine' in the Food Act 2014

The FA specifies what does and does not amount to a food in s9; importantly, whether it is "…capable of being used, or represented as being for use, for human consumption…".[222] However its exclusion of medicines is much more nuanced than its counterpart in the MA, with s9(1)(c)(iii) FA excluding "any substances used only as medicines (within the meaning of the Medicines Act 1981)…" from being a food.[223] A substance like paracetamol, for example, does have exclusive usage as a medicine, and therefore could not be classified as a food. The effect of the word 'only' is potentially problematic, for even upon a strict interpretation of this subsection, it would appear to allow for substances which

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[217] Medicines Act 1981, s3(1)(c)(ii).
[218] See 3.4.2.
[219] Medicines Act 1981, s3(1)(a).
[220] At s3(1)(c).
[221] Such a practice of not updating legislation or regulations when new legislation is imminent appears to be fairly common in this area of law, see Medsafe *Background Paper on the Natural Health Products Bill* (online, 5 September 2016).
[222] Food Act 2014, s9(1)(a).
[223] Medicines Act 1981, section 9(1)(c)(iii).

have multiple uses to be defined as a food or ingredient as well as being a medicine, given such a medicine would not fall within this subsection's concept of exclusive usage.[224]

3.4.3 The food and medicine relationship in practice

While the FA allows some crossover between foods and medicines, on a strict constructionist interpretation of MA, no medicine could meet the definition of food, and by extension, no herbal remedy (being a medicine within the definition in the MA) could be a food.[225] Given a herbal remedy may comprise any plant which has been dried, crushed, or had a similar process applied, no plant which is used as a herbal remedy could be an ingredient, and consequently a food.[226] The absurdity of this situation shows that in practice, such an interpretation is not employed, nor is likely to be enforced, but rather there is a certain interrelationship between these substances. Figure 3.1 depicts the relationship which exists in practice between foods and medicines:

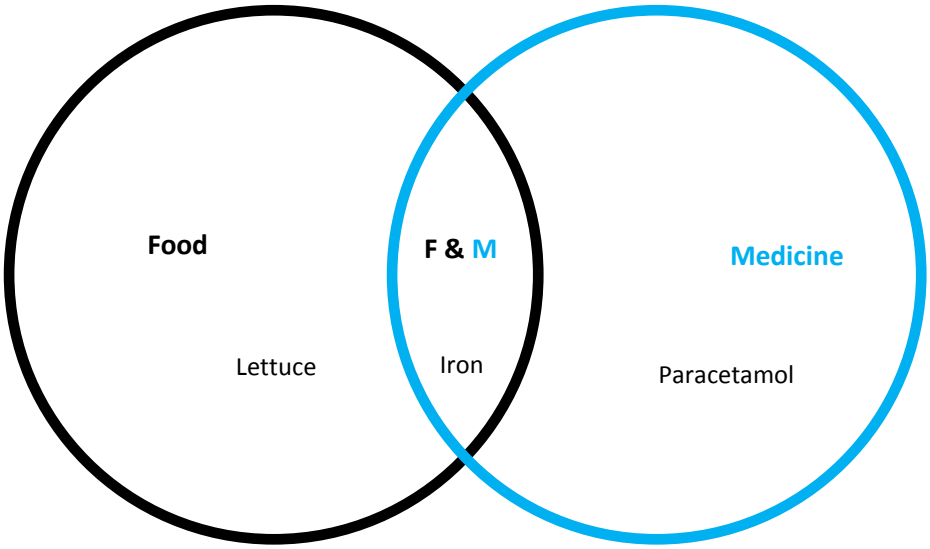

Figure 3.1: Venn diagram showing the relationship between Food & Medicine
Where: F = Food, M = Medicine

As can be seen from this Venn diagram, while most foods and medicines are independent of each other, there are some compounds like iron, which are both a food and a medicine, depending on the intent behind their presentation and usage. In the case of iron, it is a medicine when sold in capsules or tablet form, but a part of food when added to iron-fortified cereals. While iron is strictly a

[224] For example, one product with multiple uses is iron.
[225] Medicines Act 1981, s2, 'herbal remedy'.
[226] At para (a), and Food Act 2014, s9(1)(b)(iv).

constituent of food, it is important to bear in mind that the FA includes "any ingredient or other constituent of any food or drink…" as being a food for the purposes of the Act.[227]

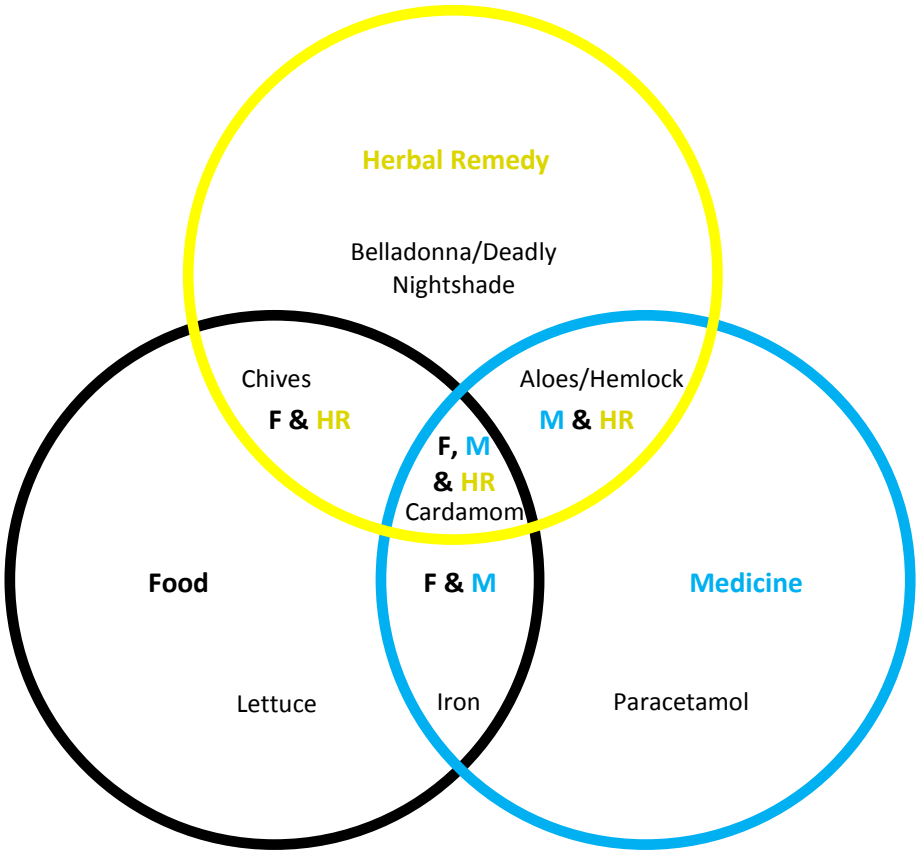

Figure 3.2: Venn diagram showing the relationship between Food, Medicine & Herbal Remedies
Where: F = Food, M = Medicine, and HR = Herbal Remedy

This Venn diagram (Figure 3.2) holds true when a third category of 'herbal remedies' are added. While the MA includes herbal remedies as medicines, this is not applicable in every instance, as shown, where some herbs or herbal remedies are not used as medicines. Cardamom compounds are one example of something which transects the artificial legislative boundaries between foods, medicines and herbs, by fulfilling each category in certain instances. When Cardamom is used as a spice, it is an ingredient and thus a food. However, when it is part of an herbal remedy for IBS, it falls within the realm of herbal medicine, and if it were to state a therapeutic purpose on the packaging, it would be a medicine as well. This begins to demonstrate the complexity inherent in devising legislation for compounds which share many similarities, but also present a plethora of individual risks. The complexity surrounding foods, medicines and herbal remedies will be revisited in more detail below when the category of DSs are added to the picture.[228]

[227] At s9(1)(b)(iv).
[228] See 4.4.

3.5 The concept of risk

In a similar manner to the new FA,[229] risk is an indispensable element in the toxicological underpinnings of medicine regulation in the MA. While the level of risk from medicines is generally much higher than that from foods, this may be appropriate given the greater benefit: a great benefit allows an acceptable risk. This brings into question how the legal and scientific conceptions of risk co-exist from practice through to legislation and litigation.

The schools of science and law have developed concepts of risk that on first appearances, seem entirely distinct. However, a detailed analysis shows that they may not in fact be unique concepts, instead sharing a somewhat symbiotic relationship.[230] This section considers these two approaches to the definition of risk, and then juxtaposes them through the example of new medicine applications, where the two fields intersect.

3.5.1 A scientific concept of risk

Risk is defined in the Oxford Dictionaries as "A situation involving exposure to danger".[231] This corresponds with the commonly accepted toxicological conception of risk; that the hazard (synonymous with danger), multiplied by the exposure is equal to the risk, as seen in Equation 2.1.

Although some scientific sources will substitute dose and time for exposure (Equation 3.1), this is effectively the same formula, given that exposure takes both these factors into account,[232] but also provides a more general scope beyond merely chemicals.[233]

$$Risk = Hazard \times Exposure$$
$$Where: Exposure = Dose \times Time$$

Equation 3.1: Variant Toxicological Risk Equation[234]

While Equation 2.1 can be quantified,[235] it generally operates as an empirical formula, rather than a numerical one, as the calculus of the hazard and exposure do not usually generate single integers. Equation 2.1 will be considered the first of two phases in the consideration of scientific risk.

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[229] See 2.4.
[230] *New Zealand Pork Industry Board v Director-General of the Ministry for Primary Industries* [2013] NZSC 154, [2014] 1 NZLR 477, at [23]-[24].
[231] *Oxford Dictionaries*, 2016, online ed).
[232] John Duffus and Howard Worth "The Science of Chemical Safety Essential Toxicology: 4 - Hazard and Risk" (2001) IUPAC <http://old.iupac.org/publications/cd/essential_toxicology/IUPACTOX4.pdf>.
[233] Ian C. Shaw *Food Safety: The Science of Keeping Food Safe* (Wiley-Blackwell, Somerset, 2012), at 15.
[234] Jos C.S. Kleinjans "Principles in toxicological risk analysis" (2003) 140-141 Toxicology Letters 311.
[235] Shaw, above n 233, at 34.

Considering the 'hazard' from a toxicological perspective will involve looking at the intrinsic toxicity of the substance. In a new medicine, for example, this will take the form of studies on how the medicine is metabolised, the structural similarities to other known molecules and their consequent effects, and acute and chronic toxicity testing.[236] Formerly, acute toxicity testing was measured as the LD_{50} of a substance; that is the lethal dose for fifty percent of the population (studied in rats or similar mammals).[237] However, with a move to more ethical forms of clinical testing, the toxicity is now primarily measured as the 'no observable adverse effect level' (NOAEL); this being the highest dose where no effect is seen from the substance in test subjects.[238] On the basis of this testing, it is then possible to forecast the chronic toxicity by dividing the NOAEL by one hundred, to obtain the acceptable daily intake for the particular substance, which is comparable to extensive reference standards, enabling a determination of the long-term effects of the compound.[239]

The 'exposure' is a simplified measurement which is informed by the toxicity testing. For example, in a medicine, the exposure takes the form of the dose which will be given to a patient over a specified period.[240]

The multiplication of the hazard and the exposure generate the risk, which is further analysed in Phase Two of a scientific risk assessment. Phase Two is much more theoretical and policy orientated than Phase One, as it involves weighing the risk alongside the benefit to determine whether the particular activity or substance is safe or worth pursuing in the context of its benefit. This is the idea of acceptable risk.

Returning to the illustration of thalidomide; if a pregnant woman was internalising a toxicological risk analysis to determine what medicine to take for morning sickness, the hazard posed by thalidomide,[241] coupled with the very low exposure required for toxicity[242] would result in an exceptionally high risk from the medicine. A Phase Two analysis would likely demonstrate high risk, while the benefit (considering the plethora of other safer medicines now available) is correspondingly low. As such, the

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[236] Food and Drug Administration "Investigational New Drug (IND) Application: Drug Development and Review Definitions" (20 August 2015) <http://www.fda.gov/>; S Parasuraman "Toxicological screening" (2011) 2(2) J Pharmacol Pharmacother. 74.
[237] Shaw, above n 233, at 16.
[238] At 16.
[239] R Walker "Toxicity testing and derivation of the ADI" (1998) 15(Suppl:11-6) Food Addit Contam.
[240] Shaw, above n 233, at 15.
[241] Israel Agranat, Hava Caner and John Caldwell "Putting chirality to work: the strategy of chiral switches" (2002) 1 Nature Reviews Drug Discovery 753, Box 1.
[242] Irene M. Ghobrial and S. Vincent Rajkumar "Management of Thalidomide Toxicity" (2003) 1(3) J Support Oncol. 194 at 196.

woman would almost certainly decide against thalidomide based on this risk analysis, as the risk is unacceptable compared to the benefit.

Conversely, thalidomide can be analysed from the opposite perspective. Consider a male who has a form of leprosy – a type II reaction called erythema nodosum leprosum. Through its inhibition of tumour necrosis factor, thalidomide has been shown to be an effective treatment for this disease.[243] While this man is not part of the typical risk group for thalidomide to cause birth defects, there are other hazards inherent in the consumption of the drug, including the risk of genetic damage being transferred to a female partner via semen.[244] Nevertheless, these are largely controllable, and the dosage or exposure is commensurate with these hazards as evidenced by the extensive research into thalidomide over the past fifty years. There is certainly a risk to this man from taking thalidomide, but the Phase Two analysis shows this risk to be controllable, lessening its probability, which when coupled with the benefits from treatment of this condition, may prove a worthwhile risk due to the benefit in this instance.[245]

3.5.2 A legal concept of risk

Risk assessment from a legal perspective is a broad subject area, ranging from risk in employment situations, to risk inherent in the insurance practice and the risk of reoffending in criminal proceedings. Each area of law and every organisation within that area has their own unique risk assessment procedures and practices, however in this instance, the primary tenets of general legal risk assessment are sought, to provide a comparison to the scientific perspective previously considered.

While some psychologists argue that there is no adequate answer to the question in risk management of 'how safe is safe enough?',[246] this potentially comes from too narrow a conception of risk based on the desire for a numerical calculus. Such an approach fails to take account of the fact that "…only in very special and crucial cases [can] anything like a mathematical (exhaustive and quantitative) study … be made."[247] Instead, legal risk assessment operates in a more theoretical capacity to judge and

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[243] Yang Degang and others "Leprosy as a Model of Immunity" (2014) 9(1) Future Microbiol. 43 at 47.
[244] Ghobrial and Rajkumar, above n 242, at 196.
[245] Thalidomide was found to be effective in the treatment of erythema nodosum leprosum (ENL) shortly after its withdrawal from the market in the 1960s, and more recently, has shown promise in the treatment of a number of cancers, including multiple myeloma. It received FDA approval for the treatment of ENL in 1998 under the brand name Thalomid, and in 2006, the same product was approved in combination with the steroid dexamethasone for the treatment of multiple myeloma. Letter from MM Lumpkin, (Deputy Center Director at the Center for Drug Evaluation and Research) to Steve Thomas (Celgene Corporation) Thalomid (thalidomide) Approval Letter: NDA 20-785 (16 July 1998), and National Cancer Institute "FDA Approval for Thalidomide" (3 July 2013) <https://www.cancer.gov>.
[246] Slovic, above n 99, at 121.
[247] Frank H. Knight *Risk, Uncertainty and Profit* (Houghton Mifflin Company, Boston, 1921), at 210-211.

weigh the various elements to ascertain the particular risk. Knightian theory[248] draws a stark contrast between scientific and economic risk assessment (the latter being akin to legal risk assessment), when the present reality is that the two are merely points on the same spectrum.[249] This spectrum ranges from pure numerical probabilities, through the empirical scientific risk assessment espoused above, to a more theoretical legal perspective, and finally the completely intuitive or inference-based Knightian perspective, which does not allow reasoned knowledge to inform the assessment.[250]

Within the concept of this spectrum, there are three theories to legal risk which merit discussion: a numerical theory, a philosophical theory, and a theory which balances the two.

Within some risk management contexts, legal risk is condensed to a mere numerical formula (Equation 3.2). While this has the benefit of allowing straightforward assessment for financial events, it does not allow scope for determination of risk in less quantifiable events.

$$Risk = Probability\ (\%) \times Loss\ of\ a\ Given\ Event\ (LGE)$$

Equation 3.2: Numerical Risk Equation[251]

When the aforementioned thalidomide example is considered in light of this equation, it is apparent that financial or insurance calculi like the loss of life or impacted quality of life arising from thalidomide consumption are well suited to this equation, as the risk of these events can be readily calculated. However, risks arising from human error rely on less definitive variables, and are thus not so readily measurable.

The opposite approach is to take a highly theoretical perspective on risk which precludes simple assessment, given the integral role which uncertainty plays in this equation (Equation 3.3). While uncertainty features in any risk calculus, the aim of the whole process is to determine an accurate assessment of the risk, based on historical outcomes or a similar means, as seen by the weighing of the probability in phase two of the toxicological risk assessment.

$$Risk = The\ effect\ of\ uncertainty\ on\ objectives$$

Equation 3.3: Theoretical Risk Equation[252]

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[248] In reference to the theories of Frank Knight from his seminal work (above) on risk and uncertainty.
[249] Knight, above n 247, at 211.
[250] At 211.
[251] Mark Little "How to Measure and Manage Legal Risk" (2 May 2014) Berkman Solutions <www.berkmansolutions.com>
[252] International Organization for Standardization *ISO 31000:2009 Risk Management - Principles and guidelines* (online looseleaf ed, ISO, 2009, accessed 18 August 2016), at 2.1.

In direct contrast to the prior adaptation of the thalidomide example, this risk equation allows no certainty or quantification within the risk analysis, which has the general effect of leaving one deeply uncertain about the risks they are engaging in by taking thalidomide. The incompatibility of this equation with the example shows the need for a risk equation to have some form of quantifiability – even in a legal context.

The third approach to legal risk is somewhat of a hybrid between Equation 3.2 and Equation 3.3, which allows the influence of quantitative certainty through the probability, while bestowing the formula with a discretionary element necessary for theoretical analysis (Equation 3.4).

$$Risk = Probability \times Legal\ Consequences$$

Equation 3.4: A Balanced Legal Risk Equation[253]

While legal consequences commonly take the form of loss, there is much more room within Equation 3.4 for the consequences to in fact be either neutral or positive outcomes compared with Equation 3.2, which purely casts this as loss. Furthermore, the term 'legal consequences' does not imbue the formula with the same preference for financial calculus as does Equation 3.2, but by adding in the statistical 'probability' qualifier, there is still more practical functionality than occurs in Equation 3.3.

Much like the toxicological approach to risk, the legal approach at Equation 3.4 still requires a second phase analysis, where the risk is weighed against the benefit to determine whether the activity is worthwhile. The key difference between this and the toxicological risk calculus is that the risk in the legal Phase Two is already informed by the probability. The reason for accounting for the probability in the first phase in the legal risk assessment is that the chance of an event occurring is to law what the exposure is to science. The probability in law and the exposure in science are the key determinants on whether the consequence or hazard will occur.

If Equation 3.4 is applied to the same example of thalidomide, it will be seen that an identical outcome is reached to that in the toxicological risk assessment, despite the differences between Phase One and Two and the respective terminology. The reason for this is that in effect, the term 'legal consequence' is the hazard inherent in a legal situation. Therefore, despite appearing quite unique and arising at different locations on the spectrum, both these equations operate in substantially similar ways, to control markedly different subject areas.

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[253] Richard Moorhead and Steven Vaughan "Legal Risk: Definition, Management and Ethics" (2015) Social Science Research Network <www.ssrn.com> at 5-11.

Returning momentarily to the FA, the phraseology 'unfit for human consumption' arises in the 1981 Act,[254] and a similar principle can be seen through s12 FA. This provides an apt example of the similar legal and scientific approaches to the risk equations, as the commentary on the FA notes in light of a couple of cases:[255] "There is no need to prove that the food would be injurious to health if it were eaten; it is a matter of degree in every case".[256] To paraphrase, regardless of the hazard posed by the food, the question of 'fitness for human consumption' or the lack thereof comes down to the amount required to have deleterious effects; that is to say the exposure.

3.5.3 The relationship of toxicological and legal risk for new medicines

While scientific risk and legal risk are similar, they differ in the types of risk, or issues to which they apply. A new medicine application is one example of this, where there are a plethora of risks on both sides which must be calculated prior to a determination on whether the new medicine will be approved; that is whether it is safe.

On the one hand, scientific risk looks at issues like the toxicity, as discussed at 3.5.1, as well as risks from interaction with other substances, environmental hazard, the effects on pregnant women, and many other potential toxicological risks from the new medicine. On the other hand, legal risks are commonly considered by the sponsor prior to filing the application to determine whether it is worth pursuing the new medicine application. Some examples of these will be the risk of infringing an existing patent, or patent application for the substance seeking approval, or the risk that the new medicine application is denied.

There are a couple of combinative risks where the legal and scientific fields merge. For example, the risk that a subject is injured from taking a medicine first requires a consideration of the hazards and exposure from a toxicological perspective to determine if or when this could happen, and to put dose restrictions in place accordingly; a practice known as risk minimisation. However, even once this analysis and subsequent phase two toxicological analysis has been conducted, there remains a possibility of adverse effects in untested populations. Such an incident occurred in the case of the anti-arthritic nonsteroidal anti-inflammatory drug (NSAID) Opren, which was removed from the market in 1982 due to many adverse effects and 61 reported deaths, primarily of elderly patients.[257]

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[254] Food Act 1981, s9(4)(a).

[255] *David Greig Ltd v Goldfinch* (1961) 105 Sol Jo 367; *Boucher v Tom The Cheap (SA) Pty Ltd* (1975) 10 SASR 257 (SA SC).

[256] Alan Henwood and others *Brookers Local Government Law in New Zealand* (looseleaf ed, Brookers), at [FD12.01].

[257] Thomas J. Lueck "At Lilly, the Side-Effects of Oraflex" *The New York Times* (Indianapolis, 15 August 1982), while the complete toxicological analysis was carried out prior to marketing, Opren was not substantially tested

Consequently, the legal risk for possible eventualities must also be weighed at the time of making the application. This risk calculus may be made by looking at the legal consequences of such an event; likely to be damages, litigation, or the rescinding of regulatory approval. These consequences will then be balanced against the probability of the event occurring, which will have been derived from the toxicological risk assessment. This demonstrates how the two forms of risk assessment both usually co-exist harmoniously, but can complement each other where necessary.

3.6 Relationship of the Medicines Act 1981 with other legislation

The MA does not act in isolation as a code, but rather draws upon a variety of other legislation to carry out its functions. The interplay between the MA and other legislation can fundamentally alter the interpretation or enforcement of the MA, and is therefore worth mentioning.

3.6.1 The Medicines Act 1981 & the Misuse of Drugs Act 1975

The MoDA is built upon a similar risk-based approach to the MA, however it classifies the three classes of drugs on a risk-based system, which relates to the harm posed by the drug to both the individual or to society by its misuse.[258] This is a somewhat more holistic approach to considering risk as opposed to a primarily empirical system as employed in the FA.

While the police play an important role in the administration of the MoDA, Medicines Control as discussed above[259] also handles the compliance with the legislation, especially insofar as the MoDA relates to medicines. While the MoDA does not define 'medicine', the MA does pay homage to the earlier Act by noting that 'controlled drug' has the same meaning as in the MoDA.[260] The MA goes on to acknowledge the close relationship between the two pieces of legislation in s109. This section's importance cannot be overlooked, as it provides for the close interworking between the two Acts, noting that they must both operate in concert,[261] although where a person bears a licence to deal with drugs under the MoDA, they are also permitted to deal with medicines under the MA;[262] a gesture to the more stringent regulations in place for handling drugs under the MoDA.

While the MA is generally a permissive statute which provides safeguards to ensure that medicines are not abused where there are substantial risks associated with their use, the MoDA is in contrast, a

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in the more elderly target audience, and the animal studies did not show the same retention, and thus did not indicate the likely liver and kidney damaged resulting from slower metabolism.

[258] Misuse of Drugs Act 1975, s3A.

[259] See 3.2.2.

[260] Medicines Act 1981, s2.

[261] At s109(2).

[262] At s109(3).

prohibitive statute, which prevents people dealing with,[263] or otherwise possessing or using controlled drugs.[264] However, the lines between the two Acts can be blurry, in that many of the substances classified in any of the three MoDA classes may in fact also come under Schedule 1 MRs.[265] While there is little written on this subject, it appears that the rationale is that in some instances, these substances operate as medicines, and thus have the evidential backing necessary to be at home in Schedule 1 MRs, but at the same time, they pose a substantial risk to individuals and society where not managed correctly, making them equally at home in the MoDA. This is another example of the fluidity which exists in the classification of products across the spectrum, from food, all the way through to Class A controlled drugs.[266]

3.6.2 The Medicines Act 1981 & the Trans-Tasman Mutual Recognition Act 1997

It is important to briefly note the TTMRA's relationship with the MA given the different way the TTMRA interacts with the FA. The MA is one of the Acts listed in Schedule 2 TTMRA, as being permanently exempt from the scope of the TTMRA such that it cannot affect the operation of the Act.[267] The applicable part of Schedule 2 clarifies this exemption: "Misuse of Drugs Act 1975, Medicines Act 1981 and Dietary Supplements Regulations 1985, to the extent that they or any of them deal with any requirement described in s10(2) applicable to therapeutic goods". Section 10 generally outlines the mutual recognition principle in relation to goods, with ss(2) specifically outlining the requirements to which goods may be subject; notably requirements like that of the goods satisfying standards with regards to their composition and quality,[268] a pertinent provision insofar as the MA is concerned.

Consequently, medicines under the MA are exempt from the requirements of the TTMRA and therefore theoretically cannot be imported and sold like any other good from Australia without ensuring compliance with NZ's regulatory framework.

3.6.3 The Medicines Act 1981 & the Health Practitioners Competence Assurance Act 2003

Practitioners' authority to prescribe medicines provides a valuable contrast to later discussions on the current and proposed dispersal of CAM products.[269]

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[263] Misuse of Drugs Act 1975, s6.
[264] At s7.
[265] See Cocaine, Codeine, Lorazepam and Methadone for example.
[266] See discussion at 3.4.
[267] Trans-Tasman Mutual Recognition Act 1997, s79.
[268] At s10(2)(a).
[269] See 4.3.1 and 5.6.

Section 2 MA lists a nurse practitioner, an optometrist, a medical practitioner, a dentist, a registered midwife, and a designated prescriber as 'authorised prescribers' under the MA who may distribute prescription medicines. These authorised prescribers, except for a designated prescriber, are empowered by professional boards or councils, whose authority is bestowed by the Health Practitioners Competence Assurance Act 2003.[270] Many of these authorised prescribers have limits to their power to prescribe, which are regulated by their professional body, usually requiring prescriptions to be within the scope of their practise.[271]

The category of 'designated prescriber' is a catch-all term which enables the MRs to specify further health professionals who may prescribe medicines.[272] The MRs employ this power, allowing veterinarians to distribute a prescription medicine for the treatment of animals,[273] but currently not specifying any further class of health professionals who are authorised to dispense prescription medicines. Whether the practical operation of the term 'designated prescriber' allows any practising member of a professional body under the 2003 Act to dispense prescription medicines remains unclear.

3.7 Conclusion

The risk-based approach in the MA was one of the earliest appearances of a well-structured, evidence based approach to the regulation of a particular category of products. While it has done an admirable job of maintaining its relevance due to sufficient flexibility throughout the legislation and the regulations, it is beginning to show its age, with difficulty keeping up with newer legislation, and the definitional problems exemplified in the legislative incongruity between food and medicine. While the Therapeutic Products Bill is set to bring medicines' regulation into the 21st Century, its enactment may still be some time away.

The risk-based approach in the MA provides a platform to consider risk management and the way scientific risk assessment is conducted in the context of goods with potentially high benefit, but correspondingly high risk. At the same time, legal risk arises in terms of secondary consequences from the risk of medicines, facilitating discussion on a variety of methods for analysing and quantifying both legal and scientific risk; methods which ultimately share much in common, despite the distinct operation of these two forms of risk assessment. Beginning with food regulation, and then medicine

[270] Health Practitioners Competence Assurance Act 2003, s114 and Sch. 2.
[271] At s21.
[272] Medicines Act 1981, s2.
[273] Medicines Regulations 1984, reg39(3).

regulation, risk is an increasingly important part of this discussion, as the perspective now turns to look at the regulation of complementary and alternative medicine products for the first time.

4 Complementary & Alternative Medicine Products

> *What we needed were facts, not opinions. Alternativists usually disagreed with this view, pointing out that conventional medicine, and pharmaceuticals in particular, were burdened with much greater risks than alternative treatments. I argued that, while this may well be so, the worth of any intervention must be seen in the context of a balance between its risks and its demonstrable benefits. If the benefits are uncertain, then even relatively small risks will weigh heavily and tilt the risk-benefit balance into the negative.*[274]

4.1 Introduction

In Chapter 2, food products were generally seen as low risk, with high benefit. In Chapter 3, medicines' risk profiles showed a relatively higher risk, but with correspondingly high benefit; justifying much more rigorous risk-based regulation of medicines. This Chapter turns to CAM products, and while the risk is usually considered to be low to moderate, in reality, the risk of most CAM products is simply not known. In contrast to medicines, CAM products have a relatively low benefit, but without an appreciation of the risk of these products, regulation of CAM products poses a real challenge.

Chapter 4 looks at the current NZ regulations for dietary supplements – the DSRs and the mechanisms by which they seek to control these products. This is followed by a broader look at CAM products and a continuation of Chapter 3's classification discussion, with the additional category of DSs. Finally, the Chapter turns to consider three examples which illustrate some of the problems associated with the DSRs since their inception more than 30 years ago.

4.2 The Dietary Supplements Regulations 1985

The DSRs are a product of their time. They were created to provide a 'catch-all' for products which are neither foods nor medicines; regulating products which provide nutritional supplementation and alleged health benefits, but do not meet the standards for medicines.[275] Utilising the extensive range of law making powers endowed by the 1981 FA,[276] the Executive created the DSRs, which remain in force more than thirty years later.[277] Neither clarifying the distinction between foods and medicines,

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[274] Ernst, above n 128, at Chapter 4.
[275] See discussion around dietary supplements when the history of food legislation was discussed at 2.2.
[276] Food Act 1981, s42.
[277] For comparison, the USA's Dietary Supplement Health and Education Act 1994 (USA) (DSHEA) should be considered. Enacted in 1994 to amend the Food, Drug, and Cosmetic Act 1938 (USA), the legislation is strikingly similar to the DSRs in its definitions, labelling requirements, statements on the label, and prevention of TCs; DSHEA, at §§6-7. The Food and Drug Administration (FDA) has very limited powers under the legislation, with an inability to address DS safety or impurity concerns until products are marketed, and no provision for handling efficacy concerns unless the products make TCs; DSHEA, at §4. Ultimately the USA's regulation of DSs demonstrates the effects of strong industry control over legislative processes when a lucrative market is at stake.

nor establishing a regulatory system requiring adherence, the DSRs have generally been marginalised by both industry and government.[278]

4.2.1 The definition of a 'dietary supplement' in the Dietary Supplements Regulations

The nascent inklings of the DSRs naturally arose during the second reading of the Food Bill.[279] It was stated here that: [280]

> How various dietary supplements offering vitamins and minerals or the so-called slimming foods or other special-purpose foods are regarded under the law will in many instances depend on how they are presented to the public. One man's food may conceivably be another man's medicine.

This theme of the presentation of DSs is interesting for the fact that it appears multiple times in the Hansard on the Food Bill,[281] and yet this theme is not present when defining DSs in the DSRs.[282]

Regulation 2A DSRs defines a DS as a liquid, powder, tablet, or lozenge[283] intended to be taken orally[284] which comprises an amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin[285] either alone or in a mixture,[286] the intention of which is to supplement those components which may be normally derived from food.[287] However the reality is that this definition does little to clarify any distinction between a DS, food or medicine, with these characteristics in reg2A applicable to all three classes.[288]

Regulation 3 DSRs specifies the maximum levels of nine vitamins and minerals permitted in DSs, however in so doing, it further muddies the waters. All of these specified products are already included in the MRs[289] or General-Sale Medicine Classification list[290] with identical maximum dose levels to those in reg3 DSRs. Consequently, all these products are general sale medicines and DSs based on their maximum daily dose. Evidently, the DSRs were never intended to classify DSs in the absence of other legislation given the overlap in both directions, and thus they will be added to the

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[278] See 4.2.4 and 4.2.5.
[279] Food Bill 1980 (158-1).
[280] (26 August 1981) 440 NZPD 2982.
[281] At 2984.
[282] Dietary Supplements Regulations 1985, reg2A.
[283] At reg2A(4).
[284] At reg2A(5).
[285] At reg2A(2).
[286] At reg2A(3).
[287] At reg2A(6); a very similar definition is used in the USA legislation – the DSHEA, which was enacted in 1994, Dietary Supplement Health and Education Act 1994 (USA), §§3 and 8.
[288] See argument on whether energy drinks come under ANZFSC or DSRs in *Sanson v Demon Drinks Ltd* HC Auckland CIV 2009-404-5464, 15 September 2009.
[289] Medicines Regulations 1984, Schedule 1, Part 3.
[290] Medsafe, above n 191.

bigger picture to determine their place in the matrix between foods, herbal remedies and medicines.[291]

4.2.2 Labelling requirements

Regulations 4-11 DSRs detail the specific requirements associated with the labelling and material attached to the packet of a DS. While the majority of these are mundane regulations relating to the labelling, two have wide-reaching implications in the marketing of DSs. For example, while not as omnipresent as it should be, consumers are accustomed to seeing the term 'dietary supplement' on the products which they buy, as required by reg5(1)(e) DSRs.[292]

Regulation 10 prohibits any false or misleading statement on or with a DS, especially one which makes claims to the nature, suitability, or effects of the DS or its ingredients.[293] While well intentioned, this is a toothless provision, as it is not included in the list of provisions for which a breach amounts to an offence under the regulations.[294] Consequently, action must be taken under the FTA if someone seeks to allege misleading or deceptive statements on a DS.[295]

Regulation 11 prohibits TCs on DSs. This regulation goes on to specify what amounts to a TC for the purposes of this regulation, giving the phrase a similar, although slightly more limited, definition to that of 'therapeutic purpose' at s4 MA.[296] As with reg10, this section is not within the scope of the offences in the DSRs. Rather it appears that if such a claim is made, then action should be taken under the MA on the basis that such a product is holding itself out to be a medicine or related product by making a TC; a position initially espoused during the second reading of the FA: "…if any special claims are made for products containing vitamins or minerals they may be regarded as medicines…".[297]

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[291] See 4.4.
[292] See results in Chapter 9.
[293] Dietary Supplements Regulations 1985, reg10(2).
[294] At reg21(1).
[295] See 4.2.4 and Chapter 7.
[296] Dietary Supplements Regulations 1985, reg11 Therapeutic claims:
"Except as permitted by the Medicines Act 1981 and any regulations made under that Act, no dietary supplement or package or container containing a dietary supplement shall be advertised or labelled with a statement relating to any of the following matters:
(a) treating or preventing disease:
(b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition:
(c) altering the shape, structure, size, or weight of the human body:
(d) otherwise preventing or interfering with the normal operation of a physiological function, whether by way of terminating or reducing or postponing, or increasing or accelerating, the operation of that function, or in any other way."
[297] (26 August 1981) 440 NZPD 2984.

Due to the difficulty and multi-legislative approach required to enforce these provisions, they are widely flouted in the industry. A MoH Regulatory Impact Statement for the NHSPB noted that over half of the 12,000 online products reviewed displayed TCs in breach of the legislation.[298]

4.2.3 A black-list or white list approach?

The DSRs employ neither a black-list nor white-list approach in their regulation of DSs. A black-list is usually a list of products prohibited from being part of the larger group – namely DSs in this case. Conversely, a white-list is commonly an exclusive list of the products which are permitted to be used as ingredients or products as part of the larger group.

Part 2 DSRs specifies nine different types of products which may be present in DSs, but it is not an exclusive list. The definition of DSs at reg2A describes a broader category of products than Part 2, and while this Part does limit some products like vitamins[299] and minerals[300] to an exclusive list, on the whole, the DSRs do not employ a white-list approach.

Neither do these regulations employ a black-list approach, for while the levels of some constituents are specified,[301] there is no outright ban on products or ingredients in the DSRs, and consequently, no black-list.

4.2.4 Penalties under the Dietary Supplements Regulations

Regulation 21(1) DSRs specifies the regulations where a breach or failure to comply, amounts to an offence. This does not include breaches of regs6-12, which regulate the labelling, consumer information, misleading statements, and TCs on DSs; with no penalties for infringing these regulations. In the event of an offence, reg21(2) goes on to detail the penalty of a fine not exceeding $500, and where the offence is a continuing one, a fine not exceeding $50 per day the offence continues. Even if that figure were adjusted for inflation, the maximum fine in 2016 would be $1,398.23: barely more than a slap on the wrist in 1985, let alone 2016 when the prices of these goods are considered.[302] There is significant fluctuation in DS pricing depending on variables like brand, ingredients and the

[298] Ministry of Health, above n 3, at 6.
[299] Dietary Supplements Regulations 1985, reg18.
[300] At reg19.
[301] At reg3.
[302] Data supplied by Reserve Bank of New Zealand "Monetary Policy: Inflation Caculator" (2017) <www.rbnz.govt.nz>; using parameters 'General (CPI)' for $500 in Quarter 1, 1985 vs. value in Quarter 4, 2016.

claims the product makes, commonly ranging from $12 to $80 for a product,[303] although it is not uncommon for some products to exceed $100 depending on the amount supplied.[304]

As a result of this nominal penalty, almost all of the few prosecutions which are taken around DSs seek to utilise other legislation. *Commerce Commission v Mega Vitamin Laboratories (NZ) Ltd*[305] was one of the earliest cases to take this approach. The case dealt with the amount of vitamins in the defendant's products, which had undergone degradation during the manufacturing process and consequently were significantly lower[306] than the amounts claimed on the label, despite still being within their 'use by' period. It was held that the defendant had made false or misleading representations as to the composition of his goods under s13 FTA. Similarly in *Commerce Commission v Zenith Corporation Ltd*[307] the defendants were prosecuted under s13 FTA for the false or misleading representations made on the weight loss product they sold, despite the fact that they advertised it as a weight loss product "…in contravention of the Food Act 1981, the Medicines Act 1981 and … the Dietary Supplements Regulations 1984."[308] *Ministry of Health v Pacific Pharmaceuticals Ltd*[309] took a slightly different approach, where the green-lipped mussel extract they sold was labelled as a DS, but displayed a number of TCs on their website. In this instance, the respondent was prosecuted under s20(2) MA for selling a new medicine without approval from the Minister.

4.2.5 The present day Dietary Supplements Regulations

Many of the problems outlined above are the result of the DSRs receiving only two amendments since their inception.[310] This appears to be the results of the move over that period towards a joint Australia-NZ regulatory scheme, and when that failed, the move towards the NHSPB. The one update which did occur in 2010 addressed two issues; updating the meaning of DS to conform with the

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[303] For example, Glucosamine products range from an RRP of $19-$122, Pharmacy Direct "Glucosamine & Chondroitin" (2017) <www.pharmacydirect.co.nz/>; St John's Wort products range from an RRP of $13-$90, Pharmacy Direct "St Johns Wort (Hypericum)" (2017) <www.pharmacydirect.co.nz/>; and general natural health products on other NZ online suppliers range from an RRP of $4-$185, HealthPost NZ "A-Z Natural Health Products Online" (2017) <www.healthpost.co.nz/>.

[304] For example, Te Kiri Gold retails at either $100 or $200 depending on the volume, Te Kiri Gold "Products Archive - Te Kiri Gold" (2017) <https://tekirigold.com/shop/>; Solgar Ubiquinol has an RRP of $139.66 on HealthPost NZ, above n 303; or Garcinia Cambogia 'Balance Naturals Ultra Ripped Protein 1.5kg' has an RRP of $171.90 on Pharmacy Direct "Garcinia Cambogia (Brindleberry)" (2017) <http://www.pharmacydirect.co.nz/Garcinia-Cambogia/>.

[305] *Commerce Commission v Mega Vitamin Laboratories (NZ) Ltd* (1994) 6 TCLR 95.

[306] At 105: between 54.4% - 87% of the claimed content.

[307] *Commerce Commission v Zenith Corporation Ltd* [2006] DCR 757 (DC).

[308] *Zenith Corporation Limited and Anor v Commerce Commission* HC Auckland CRI-2006-404-000245, 27 May 2008 at [184].

[309] *Ministry of Health v Pacific Pharmaceuticals Ltd.* HC Auckland A165/00, 16 February 2001.

[310] Dietary Supplements Amendment Regulations 2010 (SR 2010/5); Dietary Supplements Regulations 1985, Amendment No. 1 (SR 1986/378). See also Medsafe, above n 221, at 1.

separation of supplemented foods into the New Zealand Food (Supplemented Food) Standard 2010, and amending regulation 3(1) with respect to Folic Acid.[311]

Perhaps the greatest concern with the DSRs is not what is there, but rather what is not. The regulations do not regulate all the products they define as DSs, and some of the most important regulations have no mechanism for enforcement.[312] Furthermore, some aspects are missing entirely, like standards for GMP, and policies surrounding recall of unsafe products. Not only are the current DSRs insufficient, they have promulgated a 'wild-west' culture of CAM products, which is now increasingly difficult to reign in, as was seen in the progress of the NHSPB.[313]

4.3 Other products

There are two further situations where CAM or related products may not be covered in the preceding discussion. That is the dispensing of CAM products by practitioners, and the increasing incidence of supplemented food and where it fits in relation to CAM products.

4.3.1 CAM products dispensed by practitioners

There are several pieces of legislation or guidelines in addition to the MA, FA, DSRs, FTA and CGA which govern medical and CAM practitioners. This includes the Health and Disability Commissioner Act 1994, the Health Practitioners Competence Assurance Act 2003, the Code of Health and Disability Services[314] and the Tianga ā-Rongoā toolkits.[315] There are also a number of professional national or international organisations which providers of CAM modalities may belong to, however these are generally unregulated in NZ.

On the present issue, the most important legislation is again the MA, where at s32 it provides an exemption for natural therapists to manufacture or supply patients with a general sale medicine or DS.[316] In theory, this exemption only applies to patients who seek a consultation, and does not allow the therapist to advertise or state products as having a therapeutic purpose, but there is little oversight of Natural Therapists operating under this exemption.[317]

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[311] Dietary Supplements Amendment Regulations 2010 (SR 2010/5).
[312] See regs10 and 11.
[313] See 5.5.
[314] Health and Disability Commissioner *Code of Health and Disability Services: Consumers' Rights* (1996).
[315] Ministry of Health "Tianga ā-Rongoā" (23 May 2014) <www.health.govt.nz>.
[316] Medicines Act 1981, s32.
[317] Medsafe "Guidance for Natural Health Practitioners" (7 August 2013) <www.medsafe.govt.nz>.

The one NZ case which dealt with practitioners focused on misleading and deceptive conduct under the FTA when they had falsely advertised their qualifications and the efficacy of their products.[318] The issue in *Godwin* was not the dispensing of CAM products by practitioners, which they were entitled to do, but rather the broader issue of misleading and deceptive conduct, which is considered in the context of this case at 7.5.3.

4.3.2 Supplemented foods and nutraceuticals

Supplemented foods and nutraceuticals are two further categories of products which could very loosely be considered CAM products, although due to their presentation, they fit more naturally with food.[319] Nevertheless, they still warrant a brief discussion on their definition and regulation.

Supplemented foods are fairly straightforward insofar as regulations are concerned. The New Zealand (Supplemented Food) Standard 2016 was enacted under the FA 1981, and remains in force under the 2014 iteration, defining 'supplemented foods' as "…a product that is represented as a food that has a substance or substances added to it, or that has been modified in some way, to perform a physiological role beyond the provisions of a simple nutritive requirement."[320] Alongside this definition, clause 1.3 excludes dietary supplements, medicines and a number of other products from being supplemented foods.[321] The standard was intended to be an interim measure until there are supplemented food standards under the ANZFSC.[322] As noted earlier, supplemented foods were previously regulated under the DSRs, although this changed in 2010 on the basis that the requirement for modification made them distinct from foods.[323] Much like the DSRs, the Standard provides basic requirements for supplemented foods, like the requirement that they display the phrase 'supplemented food' on the label,[324] and proceeds to list a small number of restrictions, prohibitions and levels of supplements which may be added to supplemented foods.[325]

Nutraceuticals are slightly different in their nature. Perhaps the simplest definition of nutraceuticals is a food product which has natural medicinal, or antibacterial properties without the need for

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[318] *Commerce Commission v John Graham Godwin and Anor*, above n 161.
[319] This is distinct from the stance in the European Union, where food supplements include products like vitamins and minerals, making them neither food, nor CAM product, but a distinct category altogether; Directive 2002/24/EC on Food Supplements [2002] OJ L 183; European Commission "Food supplements" (24 February 2017) Europa <www.ec.europa.eu>.
[320] New Zealand Food (Supplemented Food) Standard 2016, at 1.3.
[321] At 1.3(2).
[322] At 'Purpose' (1).
[323] At 1.3(1).
[324] At 1.6(1).
[325] At 1.7, 1.10, 1.11 and 1.12.

substantial modification. Generally nutraceuticals are considered to encompass products like propolis, deer velvet and green-lipped mussels.[326] A paper produced for government in 2011 on nutraceuticals and functional foods took an in-depth look at the global market and NZ's place within it.[327] Therein, the difficulty with a single definition of nutraceuticals is discussed, although the following definition is offered: "Natural product extracts sold in dosage form (capsules, tablets, powders, etc.)".[328] Importantly, there is no specific legislation for nutraceuticals, although from that definition, it can be seen that the DSRs apply to nutraceuticals. There is little mention of the DSRs in the report, however, one of the key observations which came from discussions with industry in the preparation of the paper highlighted the importance of new legislation – specifically the early iteration of the NHSPB. Many of the stakeholders supported the Bill, in establishing a credible and world-standard legislative scheme which would promote NZ products to the world and ensure that outside countries could not ride on the coat-tails of NZ's brand in marketing their products.[329] It is likely that the NHSPB would have encompassed nutraceuticals in a much more organic manner than the DSRs, primarily as a result of such products being fairly novel, at least in the context of regulations from 1985. This will be discussed a little more in Chapter 5 when the NHSPB is considered in detail.

4.4 When a CAM product is not a CAM product: The classification debacle

As discussed at the outset, the term 'CAM' struggles to encompass the plethora of products, not to mention modalities within this form of medicine. This issue is further exacerbated when the legislation cannot determine what a CAM product is, or where one particular CAM sub-group stops and another starts.

4.4.1 Four types of products & their origins

Broadly speaking, there are four primary types of CAM products in NZ in a regulatory sense.

Herbal remedies are the first CAM sub-group. They are defined in s2 MA as previously discussed,[330] as well as being loosely referenced in reg2A DSRs. While they are defined as a medicine in s2 MA, it

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[326] Innovation & Employment Ministry of Business "Nutraceuticals" (11 January 2016) <www.mbie.govt.nz>.
[327] 'Functional foods' is another term in common usage internationally for 'supplemented foods'. In the 2011 paper, functional foods were simply defined as 'foods with added nutraceuticals', or 'foods for health', or more specifically as "Foods fortified with added or concentrated ingredients to functional levels, which improve health and performance." Coriolis *Food & Beverage Information Project 2011: Depth Sector Stream - Nutraceuticals & Foods for Health* (October 2011), at 12.
[328] At 12.
[329] At 39 and 42-43.
[330] See 3.4.3.

seems only logical from the inclusion of 'herbs' in the DSRs that they may also be a DS depending on the whim of the sponsor.

Unsurprisingly, DSs are the second type of CAM product. Certainly the most generic of all four products, DSs can be anything from daily multivitamins, to muscle-building creatine capsules. The DSRs define DSs at reg2A, but being exceedingly general and rarely enforced, this does little to delineate between DSs and other CAM products.

Homeopathic remedies are an integral part of any categorisation of CAM products, and yet they barely feature in NZ's DSRs or related legislation. The only specific mention of homeopathic remedies is in reg15(1)(d) MRs where it exempts the containers of homeopathic remedies from adherence to the labelling requirements for medicines[331] or related products.[332] On a broad interpretation of reg2A DSRs they may be included within 'edible substances',[333] however there is no authority on this issue.[334] As such, homeopathic products are effectively unregulated in the current NZ CAM product environment.

Traditional medicines are the fourth CAM product sub-group. While strictly, traditional medicines may be considered under pre-existing legislation and regulations given the majority of them comprise herbs or other edible substances, this does not do justice to the additional factors associated with traditional medicines, like the processes and historical importance of these products. In essence, traditional medicines are currently unregulated in NZ.

While there are some products which defy classification into these heads, like the aforementioned nutraceuticals,[335] or probiotics, the purpose of this grouping is to allow discussion of these products in the current legislative environment. As discussed from the beginning, the term 'CAM products' ideally avoids many of the problems associated with most classifications of such products into divisible subgroups.

4.4.2 The impact of therapeutic claims on products' classification

Generally the presence of a TC, especially a high-level claim dealing with something like cancer, will be sufficient to bring the product making that claim within the purview of the MA as either a new

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[331] Medicines Regulations 1984, reg13.
[332] At reg14.
[333] Dietary Supplements Regulations 1985, reg2A(2).
[334] While focused on homeopathic practise as opposed to products, *Commerce Commission v John Graham Godwin and Anor*, above n 161, at [72] noted that "…homeopathy and isopathy are unregulated in New Zealand at present."
[335] See 4.3.2.

medicine which is being sold without consent,[336] or as a related product; namely a food, cosmetic or dentifrice which claims to be effective for a therapeutic purpose.[337] Either way, the TC is likely to result in penalties for that product given it held itself out to be a medicine.

The leading case supporting this application of the legislation was the High Court (HC) decision in *Ministry of Health v Pacific Pharmaceuticals Ltd*.[338] In this case capsules of purified green-lipped mussel extract were distributed to a range of pharmacies in NZ. Their packaging clearly stated 'dietary supplement' in line with the regulations, and contained no TC. However, the associated website which was referenced on the label made both low and high-level TCs; regarding joint inflammation and asthma, and cancer respectively.[339] On the grounds that reg11 DSRs directly references the MA,[340] the fact that there is no penalty in the DSRs for a breach of reg11, and the general theme of the MA that TCs are restricted to medicines; the District Court (DC)[341] and HC in *Pacific Pharmaceuticals* held that the MA implicitly requires a product with a TC to be a medicine under s20 (or a related product, to which s20 applies "…with all necessary modifications…").[342] This stance is also adopted by some commentators,[343] and has been corroborated in the only other case around this issue. While distinguishing *Pacific Pharmaceuticals* on the basis of a substantially different fact pattern, the case of *Zheng v Ministry of Health*[344] supported the broad applicability of s20 MA "…to deal with cases covering a very wide range of circumstances."[345]

While penalising DSs for making TCs under the MA (as either an unregistered new medicine or related product) is uncontroversial and comes well within the interpretation of the relevant sections, it is

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[336] Medicines Act 1981, s20.
[337] At s94(1).
[338] *Ministry of Health v Pacific Pharmaceuticals Ltd.*, above n 309.
[339] At 685. *Ministry of Health v Pacific Pharmaceuticals Ltd.* DC North Shore CRN 0044017676-77, 3 August 2000; There were a variety of claims in conjunction with the products in this case, but the primary ones in question stated; "Lyprinol has a remarkable ability in reducing the inflammatory condition in mild cases of asthma", at 4; "Lyprinol reduces joint swelling by 93% compared with untreated controls" and "Lyprinol dramatically decreased the level of pain in 2-3 month period for patients suffering from osteo-arthritis" at 4; and the quote from a researcher used in marketing which stated, "If I were diagnosed with cancer I would swallow as much Lyprinol as I could handle" at 2.
[340] Dietary Supplements Regulations 1985, reg11; "Therapeutic claims
Except as permitted by the Medicines Act 1981 and any regulations made under that Act, no dietary supplement or package or container containing a dietary supplement shall be advertised or labelled with a [therapeutic claims]…"
[341] *Ministry of Health v Pacific Pharmaceuticals Ltd.*, above n 339.
[342] Medicines Act 1981, s96(1).
[343] Kate Tokeley "The Natural Health and Supplementary Products Bill: Homeopathy, the truth and the placebo effect" (2014) 26 NZ Universities Law Review 421, at 427.
[344] *Zheng v Ministry of Health* HC Auckland CRI-2007-404-384, 30 June 2008.
[345] At [26].

important to note the historic case of *Diet Tea Company Ltd v Attorney-General*,[346] which interpreted the MA in a more rigid manner. This case concerned a tea which made TCs regarding its facilitation of weight loss. There was no question that this was a TC, but instead, Henry J focused on whether tea was a food under s94(1) MA. Ultimately, he held that as the MA did not define 'food' and was a distinct, albeit companion piece of legislation to the FA, that tea could not come within the ordinary meaning of food.[347]

However, on the basis of the more recent case of *Pacific Pharmaceuticals* and the cases and commentary in support of its stance, it is likely that the Courts have moved on from such a rigid interpretation as in *Diet Tea*, and are willing to allow a certain fluidity in their identification of food, medicines and CAM products; especially where a TC facilitates this classification.

4.4.3 Food, medicine & CAM products

Having touched on the complexity of the definition of CAM products in isolation, it is worth taking a step back to consider how CAM products, and more specifically those that are currently regulated, fit in to the food and medicine regulatory schemes discussed above. Two diagrammatic aids will be used to illustrate the mêlée.

A legislative flow-chart

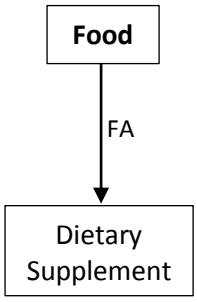

Figure 4.1: Dietary Supplements come under Food

It is first important to appreciate the inter-relatedness of food, medicines, herbal remedies, and DSs from a legislative standpoint. Foods are generally governed by the FA, which empowers the DSRs. As such, DSs can be considered a subset of foods (Figure 4.1). Similarly, medicines are governed by the MA, which includes herbal remedies (Figure 4.2). However, foods and medicines are united by two primary links. Firstly, herbal remedies can also be DSs and thus foods, and secondly, DSs can also be medicines either as herbs, or by way of TCs (Figure 4.3). Therefore, the attempt at an impenetrable barrier between foods and medicines espoused by the MA[348] does not exist in practice, for while an argument may be made for products not co-existing as both medicines and foods

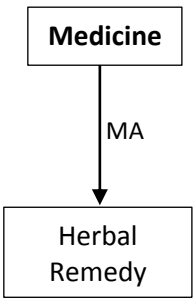

Figure 4.2: Herbal Remedies come under Medicines

[346] *Diet Tea Company Limited v Attorney-General* [1986] 2 NZLR 693 (HC).
[347] At 9-10.
[348] See 3.3.1; and Medicines Act 1981, s3(1).

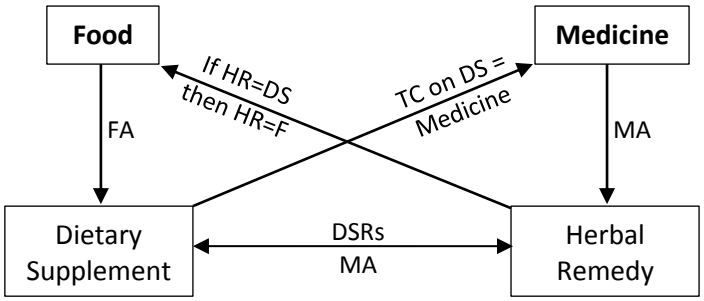

Figure 4.3: Legislative relationship of Food, Medicine, Herbal Remedies and Dietary Supplements
Where: HR = Herbal Remedy, and F = Food

simultaneously, there is no doubt that the same product could be a medicine or a food, depending on its presentation and marketing.

A return to the Venn diagrams

In the previous chapter at 3.4.3, the following Venn diagram was used to depict the overlap between food, medicine, and herbal remedies.

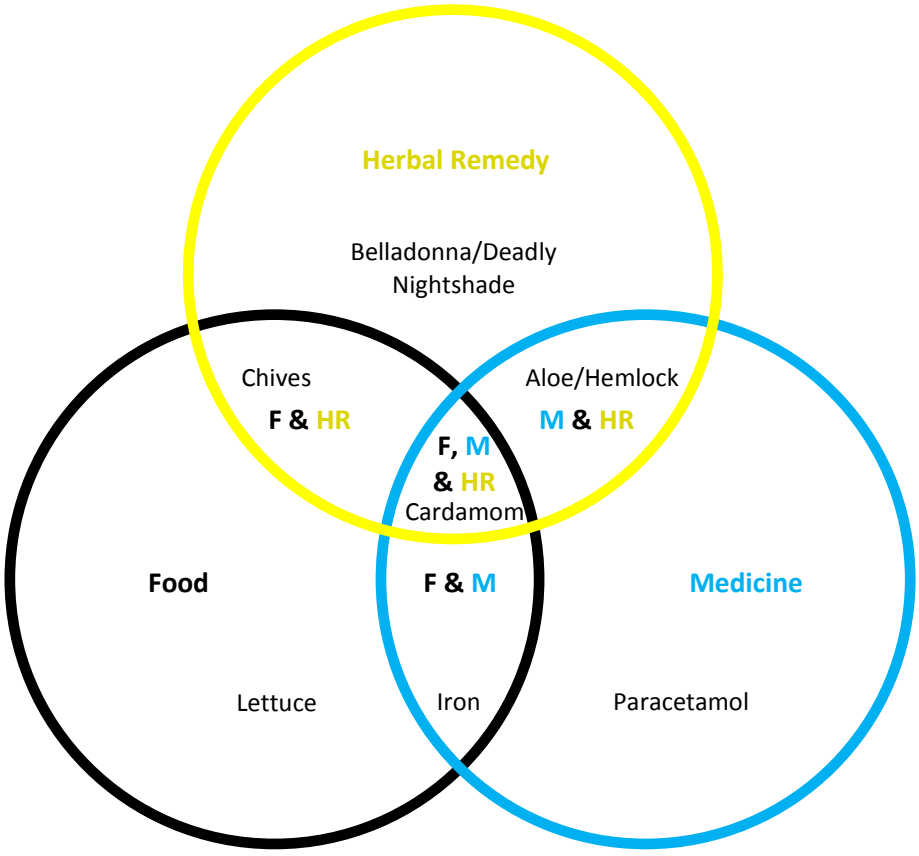

Figure 4.4: Venn diagram showing the relationship between Food, Medicine & Herbal Remedies
Where: F = Food, M = Medicine, and HR = Herbal Remedy

Through the logic of Figure 4.3, it now becomes clear that merely adding DSs to the Venn diagrams employed at 3.4.3, does not adequately depict the legislative relationship of these four products (Figure 4.5). There are multiple reasons for this, but two which cripple this style of Venn. The spaces in the 'herbal remedy' and 'DS' circles which presume these two can exist without being either

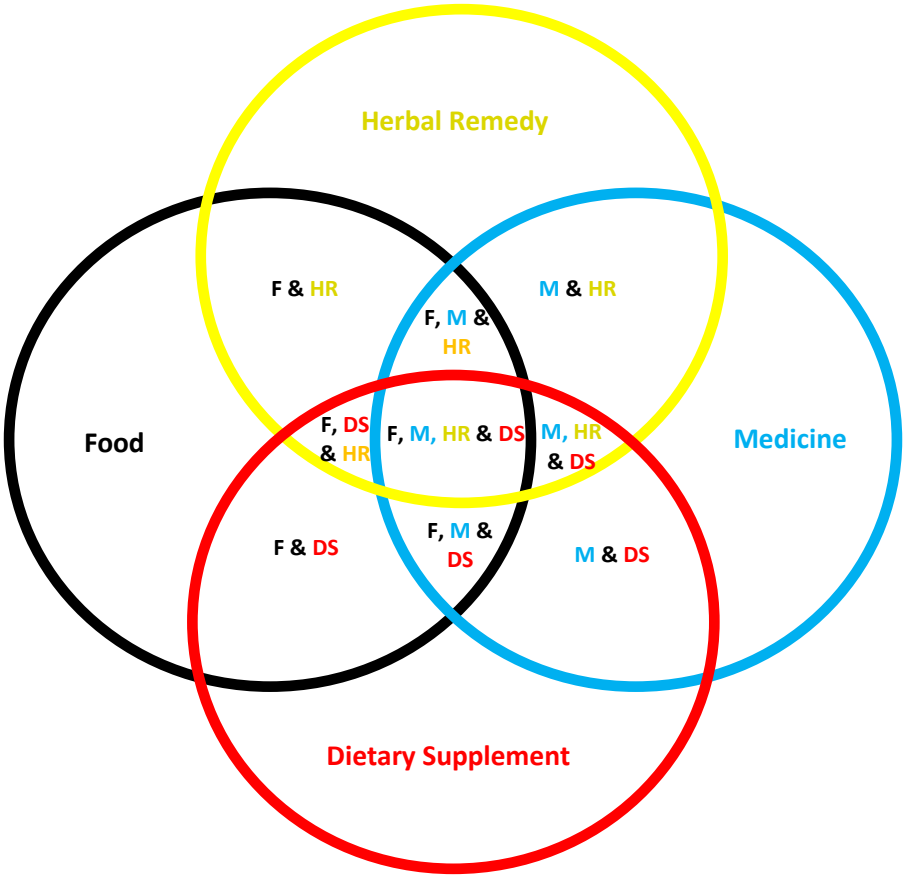

Figure 4.5: Venn diagram of Food, Medicine, Herbal Remedies and Dietary Supplements
Where: F = Food, M = Medicine, HR = Herbal Remedy, and DS = Dietary Supplement

medicine or a food is false; as shown by Figure 4.3. Secondly, even if that were not an insurmountable issue, this style of Venn diagram does not allow for two overlaps: that between herbal remedies and DSs, and that between foods and medicines. While it is possible to construct an adaptation of a Venn diagram which accounts for all possible permutations (Figure 4.6), this starkly illustrates the impossibility of this diagrammatic representation of the legislative relationship, through the exact links it sought to make: that between food and medicines, which are unquestionably mutually exclusive by way of s3(1)(c)(ii) MA. While in theory, it is possible to create Venn diagrams which come close to representing the current legislative relationship between these four products (Figure 4.7), they are all premised on the basis that at some level in the subsets of 'DSs' and 'herbal remedies',

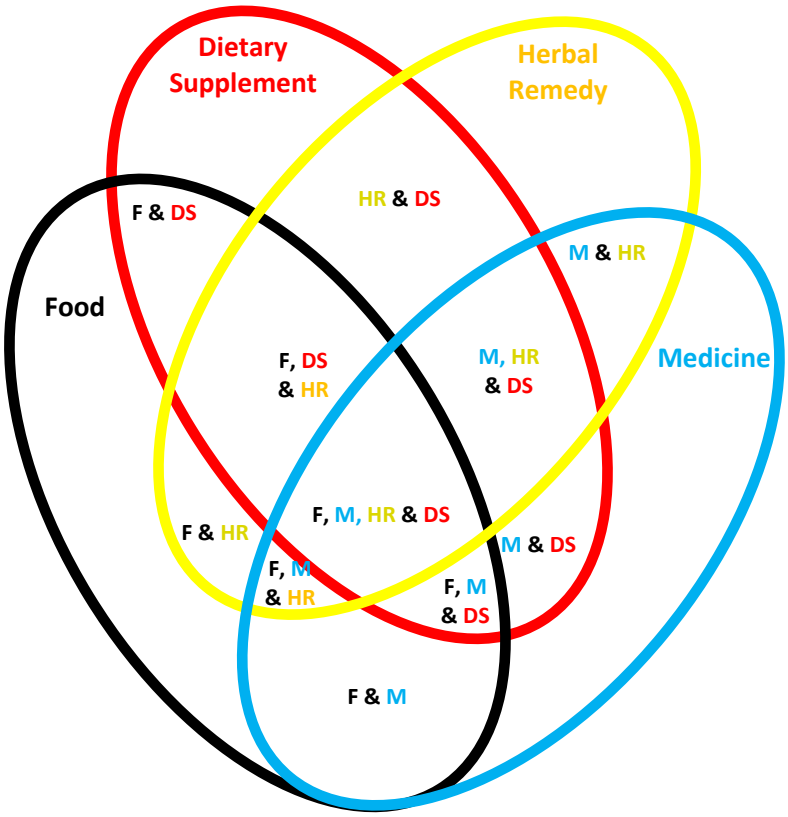

Figure 4.6: Adapted Venn diagram for Food, Medicine, Herbal Remedies and Dietary Supplements
Where: F = Food, M = Medicine, HR = Herbal Remedy, and DS = Dietary Supplement

there is cross-over between medicines and foods, which is not supposed to be the case. As seen in Figure 4.7, any depiction which comes close is practically unworkable.

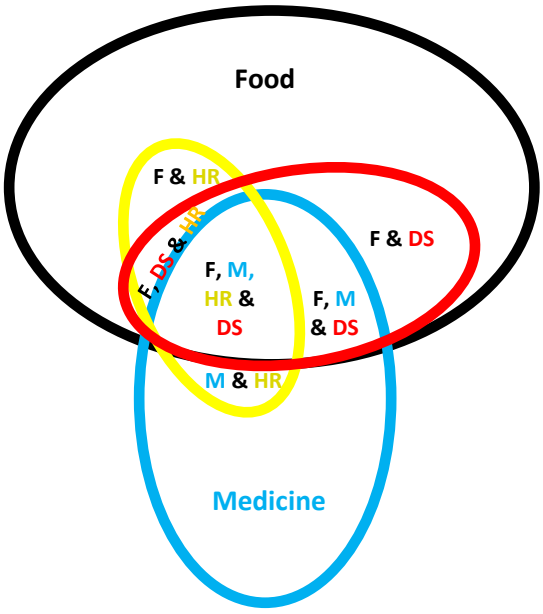

Figure 4.7: A close graphical representation of the classification relationship
Where: F = Food, M = Medicine, HR = Herbal Remedy, and DS = Dietary Supplement

There are two possible work-arounds for this conundrum. The first approach, and that likely to be taken by the courts, were this ever to be an issue, would be to assess each case on its own merits, devoid of context or other examples which highlight the impossible relationship between these related products. For example, Manuka honey is commonly cited as having medicinal properties, being accepted in an obiter statement in the CA that it does have health benefits as a wound dressing.[349] Similarly, it was observed in the debate on the NHSPB that honey is a therapeutic product, a food, and a supplementary product.[350] If the question of honey being a medicine came before the courts, it is almost certain that they would deem it a related product under s94(1) MA, thus avoiding any conflict between the FA and MA. Honey is a straightforward example, however the problems are immediately apparent if a CAM product like silver, or garlic came before the courts, due to their crossover between medicines and DSs, or foods and herbal remedies respectively. Silver is a general sale, or pharmacy only medicine depending on the concentration, but is also commonly present as 'colloidal silver' in a number of CAM products, while garlic powder is frequently added to capsules or other CAM products, as well as being a common ingredient in food. To avoid a conflict between the legislation, a court is likely to adopt any one of a number of canons of statutory interpretation, ranging from the rule *generalia specialibus non derogant*, meaning that general provisions do not take precedence over specific ones, to *leges posteriors priores contrarias abrogant,* where later legislation takes precedence over earlier legislation. The court's approach will turn on the facts of the case, but the important point is that the court will do all in its power to avoid deeming the legislation incorrect or contradictory.

However, from an academic perspective, the legislative issues between the classifications of these four products arise due to the incongruous provisions in different statutes. Occam's razor dictates that the simplest explanation should prevail, and in this instance, that explanation is that the conflict between CAM products, foods and medicines under the current legislation is a result of piecemeal legislative development, coupled with radical changes in the nature and diversity of CAM products over the past three decades, rendering the legislation contradictory and unworkable.

4.5 The problems inherent in the DSRs

At the beginning of this chapter, the nature of the DSRs were considered, somewhat devoid of context. Section 4.4 then turned to look towards one of the problems with the DSRs in light of associated

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[349] *Honey New Zealand (International) Limited v Director General of the Ministry for Primary Industries*, above n 160, at [41].
[350] (20 March 2013) 688 NZPD 8810; per Hon Maryan Street MP.

legislation and the definitions therein. This section continues that theme, but turns more directly to the question of why there is a need to change the existing CAM product regulations. Alternatively, the question may be posed as: 'What are the problems which make the DSRs untenable for the future regulation of CAM products?'

While there are countless issues which could be considered, three pertinent NZ examples will be employed to demonstrate a variety of harms, or problems which exist under the current regulations.

4.5.1 The Pan Pharmaceuticals recall

In 2003, one of the biggest crises around CAM products in Australia and NZ came to the fore. Nearly 1600 products produced by Australian company Pan Pharmaceuticals were recalled as a result of serious adverse reactions to the Pan product 'Travacalm', for preventing motion sickness, with 19 people requiring hospitalisation due to life threatening reactions.[351] This occurred due to a huge variation in the quantity of active ingredient present in the product,[352] ranging from 0-700% of the advertised amount.[353] Upon further audit, it became apparent that this issue of "manipulation", "fabrication", and "substitution"[354] was somewhat endemic throughout the manufacturing and testing of Pan Pharmaceuticals products, resulting in the recall and license suspension by Australia's medicine and CAM product regulatory body, the TGA.[355]

Naturally, this recall was of grave concern to food safety and medicine authorities in NZ. This was further exacerbated by the fact that Pan manufactured a number of products for other companies which were popular in NZ, including Red Seal, Nutralife and Thompson Nutrition.[356] While the issue of unsafe and substandard products is exceedingly concerning, and shall be discussed further below,[357] the uniquely NZ problem in the context of the Pan Pharmaceuticals case was the difficulty with which the recall was executed.[358]

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[351] Bebe Loff and Helen McKelvie "Australia shaken by complementary medicines recall" (2003) 361 The Lancet 1710; Bob Burton "Complementary medicines industry in crisis after recall of 1546 products" (2003) 326 BMJ 1001.

[352] The active ingredient in Travacalm which was causing problems due to the huge fluctuations in the quantity present in these products was hyoscine hydrobromide.

[353] Thomas Faunce and Esme Shirlow "Recent Legal Developments and the Authority of the Australian Therapeutic Goods Administration" (2009) 16 JLM 764.

[354] Burton, above n 351.

[355] Loff and McKelvie, above n 351.

[356] Reuters "NZ orders recall for Pan products" *NZ Herald* (online ed, Auckland, 2 May 2003).

[357] See 4.5.2.

[358] At the same time, the proposal for a joint therapeutic products agency was at the forefront of public attention, and consequently, the Pan Pharmaceuticals recall was used as a political football by a variety of people to further their own arguments; see further at 5.3.1.

Two elements do warrant noting. Firstly, while many detractors of the joint-agency vitriolically condemned the TGA for failing to pick up on the Pan Pharmaceuticals' issues sooner,[359] the fact the issues were identified at all is testament to the post-marketing surveillance, adverse event reporting and the rigorous powers of the TGA to audit and control therapeutic goods in Australia. Such a wide-scale operation against a manufacturer who, at the time, produced about 70% of Australia's CAM products could simply not occur under the DSRs in NZ.[360]

The second, and more pertinent issue for NZ is the execution of the recall of Pan products. On 30 April 2003, the Health and Food Safety Minister, Annette King made a statement acknowledging the Australian recall, highlighting the problem with a similar response in NZ.[361] This is the fact that there is no register of CAM products in NZ, making a widespread recall of goods produced by one manufacturer quite difficult.[362] Of the 219 products initially recalled, only three were medicines in NZ, with the remaining 216 products classified as foods.[363] Consequently, these products had to be recalled under s40 FA 1981 on the basis that the 'food' was unsound, or unfit for human consumption.[364] Due to the lack of a register, recalling the vast majority of these products came down to an ad-hoc process, which required retailers, importers and other stockists of any of the products highlighted in the recall to destroy or return these products. There was considerable confusion around the recall in NZ, with the process taking many days, and several different recall documents before all the information was available, due to an array of problems ranging from different names of the Australian equivalent products, to the sheer volume of products to be recalled – 642 DSs in NZ.[365]

The failings of the DSRs in managing any kind of recall are epitomised by the NZFSA director of policy and regulatory standards who at the time noted: "We just don't have a handle on the scope of the New Zealand industry."[366] The inability to recall CAM products under the DSRs, and the lack of any kind of database of either CAM products, or the manufacturers, suppliers and importers of CAM

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[359] Sue Kedgley "PAN Pharmaceutical Scare" *Scoop* (online ed, 12 May 2003)364.
[360] Burton, above n 351.
[361] Annette King "Australian Recall of Pan Pharmaceutical Products" (press release, 30 April 2003).
[362] See above that Pan manufactured some products for a variety of NZ brands, including Red Seal, Nutralife and Thompson Nutrition, complicating the recall procedure despite the fact it was a single manufacturer whose products were potentially impaired.
[363] Lynne Eagle and others "Regulatory Oversight or Lack of Foresight? Implications for product recall policies and procedures" (2005) 28 Journal of Consumer Policy 433, at 435.
[364] Kedgley, above n 359.
[365] NZ Herald "List of Pan Pharmaceuticals products sold in NZ released" *NZ Herald* (3 May 2003).
[366] At 1.

products in NZ amounts to a major problem in terms of ensuring product safety and consumer protection.

4.5.2 Contaminants, fillers, and the corresponding false labelling of CAM products

In 2013, researchers in Canada published an article recounting the results of a study which used DNA barcoding to determine the purity, or lack thereof, in North American herbal products.[367] They isolated the DNA of 44 products available in Canada or the USA from 12 different suppliers, and compared this to a standard reference material herbal barcode library to ascertain whether the product was authentic, or if there was substitution, contamination or a filler material present in the herbal product.[368] While the study acknowledged the possibility of error in using only three or four herbal product samples from a small selection of companies, their results showed that the products from only two of the 12 companies were authentic with no substitution, contaminants or fillers.[369] These results are more stark when it is seen that only 48% of the products were able to be authenticated, 59% of the products displayed evidence of substitution with species not on the label, and 33% of the authenticated products showed the presence of contaminants and fillers,[370] as seen in Figure 4.8.[371]

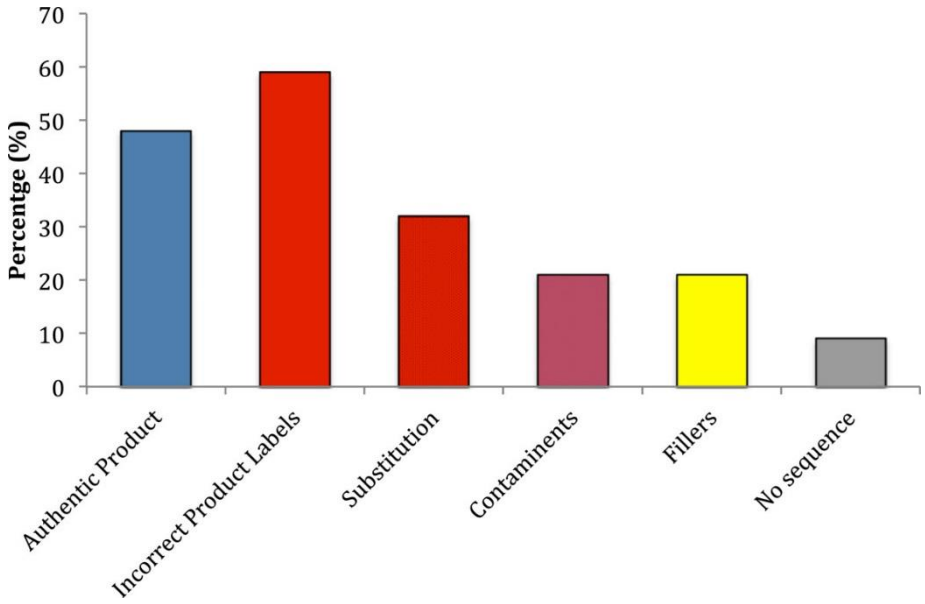

Figure 4.8: DNA barcode results from blind testing of the 44 herbal products representing 30 medicinal species of plants

[367] Newmaster and others, above n 4.
[368] At 2-3.
[369] At 5.
[370] At 4-5.
[371] Image reproduced from Newmaster and others, above n 4, Figure 2, under Creative Commons Attribution License 2.0 permitting unrestricted use, distribution, and reproduction in any medium, providing the original work is properly cited.

These results are highly concerning on a number of levels. The risks posed by imbibing a product which is of a different species and not present on the label, or more alarmingly, a product which is contaminated or consists of filler materials, could pose a risk of either acute toxicity, or serious allergic reaction. Furthermore, from a legal and regulatory perspective, there is a major problem when products are marketed as something they are not, or when the label does not correspond to what is inside the container.[372]

Although this study is somewhat geographically removed from NZ, it would be naïve to dismiss the gravity of its results on this basis, given that the regulations in the USA are akin to NZ's DSRs, and Canada's regulations are more comprehensive.[373] Proponents of lower regulation, or a self-regulating industry for CAM products take pleasure in citing a lack of evidence of harms, which they claim justifies a very low risk profile for CAM products.[374] However this ignores the wealth of information and evidence indicating a dangerously cavalier attitude which pervades CAM product manufacturing with respect to the purity, authenticity, safety and GMP, as seen in both the Pan Pharmaceuticals case[375] and in the Newmaster research.[376]

One further example demonstrates the severity of this issue in NZ. In 2015 the NZ Herald began an investigation into workout supplements which came under the DSRs. Commissioning testing by the Crown Research Institute ESR, the Herald found the banned stimulant DMBA[377] in sports supplements available in NZ.[378] This went hand-in-hand with evidence of the death of a NZ airman in 2009 from a supplement containing DMMA,[379] a close analogue of DMBA.[380] An Official Information Act[381] request in the investigation also revealed two NZers who had contracted acute non-viral hepatitis from a

[372] See further discussion on the Fair Trading Act at Chapter 7.
[373] Ellena, above n 9, at 115; Joseph Volpe *Natural Health Products: A New Vision* (Standing Committee on Health, November 1998), this report was adopted in its entirety for the regulation of Natural Health Products in Canada.
[374] Appleton Associates Limited "Joint Industry Natural and Traditional Health Products Bill 2009" (February 2012) at 6-7; Health Freedom NZ Trust "Submission to the Health Committee on the Natural Health Products Bill 2011" (24 February 2012) at 4-6.
[375] See 4.5.1.
[376] Newmaster and others, above n 4.
[377] 1,3-dimethylbutylamine.
[378] Steve Deane "Pre-workout supplements: Makers a step ahead of law" *The New Zealand Herald* (online ed, Auckland, 11 February 2015).
[379] 1,3-dimethylamylamine.
[380] Steve Deane "'It was like a drug, it was addictive. You had to wean off it' - The damaging effects of the gym-drug roundabout" *The New Zealand Herald* (online ed, Auckland, 9 February 2015).
[381] Official Information Act 1982.

different supplement.[382] More than six-months later, another restricted drug, Picamilon, a precursor to the date rape drug GHB, was found in a number of supplements.[383]

While the CAM product industry may try to distance itself from workout supplements and the litany of toxic and illicit drugs found therein, two facts are unavoidable. The workout supplement industry currently exists largely under the ambit of the DSRs, and therefore there is no reason to presume CAM products are not subject to the same problems. Secondly, the attempts of the industry to claim that no evidence of harm is good evidence, is an illogical and dangerous stance, when the little scientific evidence which does exist around such products, prompts serious questions about the nature and safety of the CAM product industry as it currently exists.

4.5.3 Medicine & CAM product adverse interactions

The final issue to be considered here when looking at the effectiveness of the DSRs is the matter of adverse reactions resulting from a combination of medicines, or medical procedures with the consumption of CAM products. This is a well-documented area of research, so little time will be spent dwelling on it.

Nevertheless, it is important to acknowledge the multifarious harms which come from a lack of regulation of CAM products, and ensuing reactions with medicines. One of these is the lack of information around the actual constituents of CAM products on the market, as previously discussed,[384] and the havoc which these unknown ingredients may reap on the body, either alone, or in combination with medicines. This is a particularly difficult situation, given the dearth of information which both consumers, and healthcare professionals may have as to the cause of the adverse effects.

Even in the event that the CAM product which a patient has consumed is exactly what is labelled on the bottle, medical experts frequently struggle with the interactions due to an unwillingness on the patient's behalf to disclose the CAM product, or products which they are taking.[385] While this is a problem in prescribing medication to patients due to interactions which may otherwise be avoided, it is an even greater risk in surgery, when the earlier consumption of CAM products can result in any

[382] Deane, above n 380.
[383] Steve Deane "Date rape drug ingredient in fitness booster" *The New Zealand Herald* (online ed, Auckland, 20 October 2015).
[384] See 4.5.2.
[385] Michael Thomsen, Hanni Gennat and Mathias Schmidt "Herb-Drug Interaction" in Ronald R. Watson and Victor R. Preedy (eds) *Botanical Medicine in Clinical Practice* (CABI, United Kingdom, 2008) 859, at 862.

number of problematic occurrences; from interference with blood clotting,[386] to rejection of transplants,[387] and heightened effects of sedatives or anaesthetics.[388]

The effects seen in these products are both good and bad news for the CAM product industry. Extensive research in the past decade has looked into the therapeutic effects of St John's Wort, with the results showing that it has a serious effect on the Cytochrome P450 proteins; more specifically that it speeds up the activity of one specific enzyme involved in the metabolism of more than 50% of medicines.[389] The results of this are numerous, and include lower drug levels and consequently lower effect, hypertension, arrhythmia, thromboembolism and serotonin syndrome.[390] While the herbal remedy is clearly having a therapeutic effect, the evidence begs the question of whether it should instead be regulated as a medicine, given there is no provision within the DSRs to handle the vast array of complexities associated with St John's wort and medicine interactions, let alone the host of other products which may cause similar adverse interactions. As an aside, St John's wort provides a neat illustration of the fact that coining a remedy or medicine "natural" in no way means that it is safe.[391]

While on its own, these interactions are not reason enough to prohibit allowing people to make some choices for their own health and wellbeing, there is a definite need to recognise the risks involved when people self-treat with CAM products in conjunction with medicines, without involving a medical professional in that decision-making process. Currently, there is no requirement for DSRs to include a statement on the label to 'consult your healthcare professional in the event of side-effects, or if symptoms persist'. Coupled with the fact that there is an increasing amount of stigma around CAM products due to their relative lack of regulation, it is unsurprising that patients withhold information from their doctors on the cocktail of CAM products they may be taking, in turn increasing their risk of adverse reactions.

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[386] Feverfew, ginger, cranberry, St John's Wort, ginseng, garlic, glucosamine, chondroitin and flavocoxid are all documented as affecting blood clotting or interacting with anti-clotting pharmaceutical products like Warfarin. See American Academy of Orthopaedic Surgeons "Herbal supplements may cause dangerous drug interactions in orthopaedic surgery patients, study suggests" *ScienceDaily* (online ed, 11 October 2011).

[387] Garlic and St John's Wort show evidence of interacting with immunosuppressant drugs, which can lead to transplant rejection; at 1.

[388] Valerian and motherwort cause exaggerated effects from sedatives, intensifying anaesthetics and potentially resulting in a coma; at 1. Ara Tachjian, Viqar Maria and Arshad Jahangir "Use of Herbal Products and Potential Interactions in Patients with Cardiovascular Diseases" (2010) 55(6) J Am Coll Cardiol. 515.

[389] St John's wort "…induces the hepatic cytochrome P450 system, particularly CYP3A4, an enzyme involved in oxidative metabolism of more than 50% of all prescription medications." at 517.

[390] Tachjian, Maria and Jahangir, above n 517-518.

[391] See further discussion on this at 5.6.1.

4.6 Conclusion

Despite the ramifications of section 4.5, it is important to bear two points in mind. Firstly, while the risks and harms considered above are a very real problem, purely on the basis of the free-market's self-regulation it is likely that the majority of CAM products pose little risk. Nevertheless, it is vital to recall the fact that given the dubious benefits surrounding the majority of CAM products, even a little risk could be unacceptable when the benefit is so minimal, and new regulation should propose strategies for ascertaining and managing this risk in a proactive manner.

This brings the discussion full circle, illustrating the second point, the overarching problem which section 4.5 sought to illustrate; namely that these issues exist due to the "…permissive laissez-faire [DSRs] which in practice amounts to deregulation."[392] The combination of the outdated DSRs with the problems highlighted at 4.5, and the confusion around classification of DSs at 4.4 demonstrate why almost all stakeholders agree that new regulation for CAM products is long overdue. Nevertheless, the question remains, whether the most recent proposed mechanism for addressing this problem, in the form of the NHSPB, would adequately rectify the situation.

[392] von Tigerstrom, above n 31, at IV.

5 The Natural Health and Supplementary Products Bill

Even if one particular alternative therapy was entirely devoid of risk … we still have to consider its indirect risks, by far the most important of which is the possibility that a patient will avoid an effective mainstream treatment in favour of an ineffective alternative option.[393]

5.1 Introduction

This Chapter turns to the history of CAM product regulation since the DSRs; most notably the numerous proposals for regulating CAM products in NZ. The Chapter focuses on the most recent proposal; the NHSPB and its legislative history, and the nature and details of the Bill.

The NHSPB was withdrawn from Parliament on 8 November 2017, but posed the best attempt at CAM product regulation in NZ to date, despite its numerous flaws. It also made the most progress of any proposal so far, passing its second reading in Parliament.

5.2 Issues in CAM Product Regulation

Before delving into the practical details, a brief discussion on three key principles of CAM product regulation is warranted. This provides some prescience to the ensuing analysis by first addressing a couple of the matters which permeate the history of CAM product regulation in NZ.

The first issue is that of risk in relation to CAM products, which informs the second issue of government paternalism over CAM products. Finally, the principled argument that proponents of CAM products frequently raise of the 'right to choose' is considered alongside issues of autonomy and self-determination in healthcare decision, as well as the possibility of a limited 'right to choose'.

5.2.1 Risk

There is no need to extensively reiterate the risk-benefit discussions of an earlier chapter,[394] but it is important to note this metric for determining the level of 'acceptable risk'. When the risk is high, the benefit must be similarly large to offset the risk and thus make it acceptable. When the risk is low, however, the benefit does not need to be equally low in order for the risk to be acceptable. The problem with applying risk-benefit analyses to CAM products is that the benefit is often very low, but the risk uncertain, which poses a uniquely difficult situation. If the benefit of CAM products is low, to very low, then the risk must be infinitesimal in order for it to be acceptable. In an ideal world the solution to this problem would be to determine the hazard of each product, allowing a proper risk

[393] Ernst, above n 128, Chapter 5.
[394] See 3.5.

assessment to take place, however on the basis of practicalities alone this would take years and would be unlikely to have stakeholder support.

The MoH recently identified an Australian report from 2005 which recorded about 400 adverse events each year, and 62 deaths in the previous ten years from CAM products.[395] However, these figures are widely considered an under-estimate,[396] and the market has grown exponentially in the past decade, and presumably so too have the hazards, leaving the risk of these products inherently uncertain.

5.2.2 Paternalism

As the risk of CAM products is unknown, the question of the appropriate level of regulation for CAM products becomes increasingly complex. Regulation inherently involves restrictions on the freedoms of individuals, but modern society recognises that a restriction of liberty can be justifiable if it prevents harm to self or others.[397] The harms from CAM products and a rigorous adherence to them are multifaceted, often going beyond the harms directly caused by the products themselves, to indirect harms including; harm from giving CAM products to young children or the elderly, reliance on CAM instead of competent medical care, and adverse reactions between CAM and medicines.

Any action which causes harm to another, like parents medicating children with CAM products which at best may not work, and at worst may cause worsening or additional problems, can be a serious matter which permits a relatively high level of paternalism. Conversely, at such a time when either the benefits of CAM products can be demonstrated to be as good as, or better than evidence-based medicine, or a lower degree of hazard is established, then a correspondingly lower degree of paternalism should apply.

5.2.3 Right to choose

The issue of paternalism struggles with the idea that individuals have a 'right to choose' their own healthcare.[398] The 'right to choose' and healthcare have long been in conflict; for example, with the

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[395] Ministry of Health, above n 3, at 4.
[396] At 4.
[397] While Mill's harm principle dictates that power can only be exercised over people in order to prevent them harming others, a more restrictive approach is generally applied in practice, whereby people are restricted from causing harm to themselves through regulation from the requirement to wear seatbelts, through to the ability under common law to restrain a person in a medical setting if the pose a harm to either themselves or others.
[398] *Airedale NHS Trust v Bland* [1993] AC 789 (HL) is one of the leading cases on autonomy in a healthcare setting; "The first point to make is that it is unlawful so as to constitute both a tort and the crime of battery, to administer medical treatment to an adult, who is conscious and of sound mind, without his consent… Such a person is completely at liberty to decline to undergo treatment, even if the result of his doing so will be that he will die." at 857.

'woman's right to choose' in abortion cases, and the desire of anti-vaccination campaigners to have a 'right to choose' whether to vaccinate their children.

Vaccinations provide a useful comparison to the present issue. Some countries are beginning to impose sanctions accompanying a failure to vaccinate dependent children.[399] This is due to a recognition of the overwhelming benefit of vaccinations to both the individual, as well as society more broadly, along with the minimal risk associated with them.

CAM product regulation, in comparison, sits closer to the grey area. To a certain extent, there is a need to protect the public, often from themselves, and inherently this will limit their right to choose. In the case of CAM products, it is difficult to argue that this is not warranted when proponents claim they can be as effective as, if not better than, medicines, and yet there is little evidence on either their safety or efficacy. One possible solution which balances these seemingly competing interests is a limited right to choose, where consumers can choose products which are efficacious and low risk, thereby incentivising companies to conduct the necessary research to ascertain the effect and safety of their products.

[399] Erin Walkinshaw "Mandatory vaccinationa: The international landscape" (2011) 183(16) Canadian Medical Association Journal 1167. Australia has restrictions in place for unvaccinated children, with proposals for fines where unvaccinated children enter preschool; Adam Baidawi "'No Jab, No Play': How Australia is Handling the Vaccination Debate" *The New York Times* (online ed, New York, 24 July 2017). France is making vaccination mandatory from 2018; Katie Forster "France to make vaccination mandatory from 2018 as it is 'unacceptable children are still dying from measles'" *The Independent* (online ed, London, 5 July 2017). Germany has fines of up to €2,500 if parents fail to seek medical advice about vaccinating their children; BBC News "Germany vaccination: Fines plan as measles cases rise" *BBC* (online ed, Europe, 26 May 2017). Italy has also introduced mandatory vaccination for children, with fines or the risk of losing custody where parents fail to vaccinate; Christopher Livesay "Amid Measles Outbreak, Italy makes Childhood Vaccinations Mandatory" *NPR* (online ed, Washington, 19 June 2017).

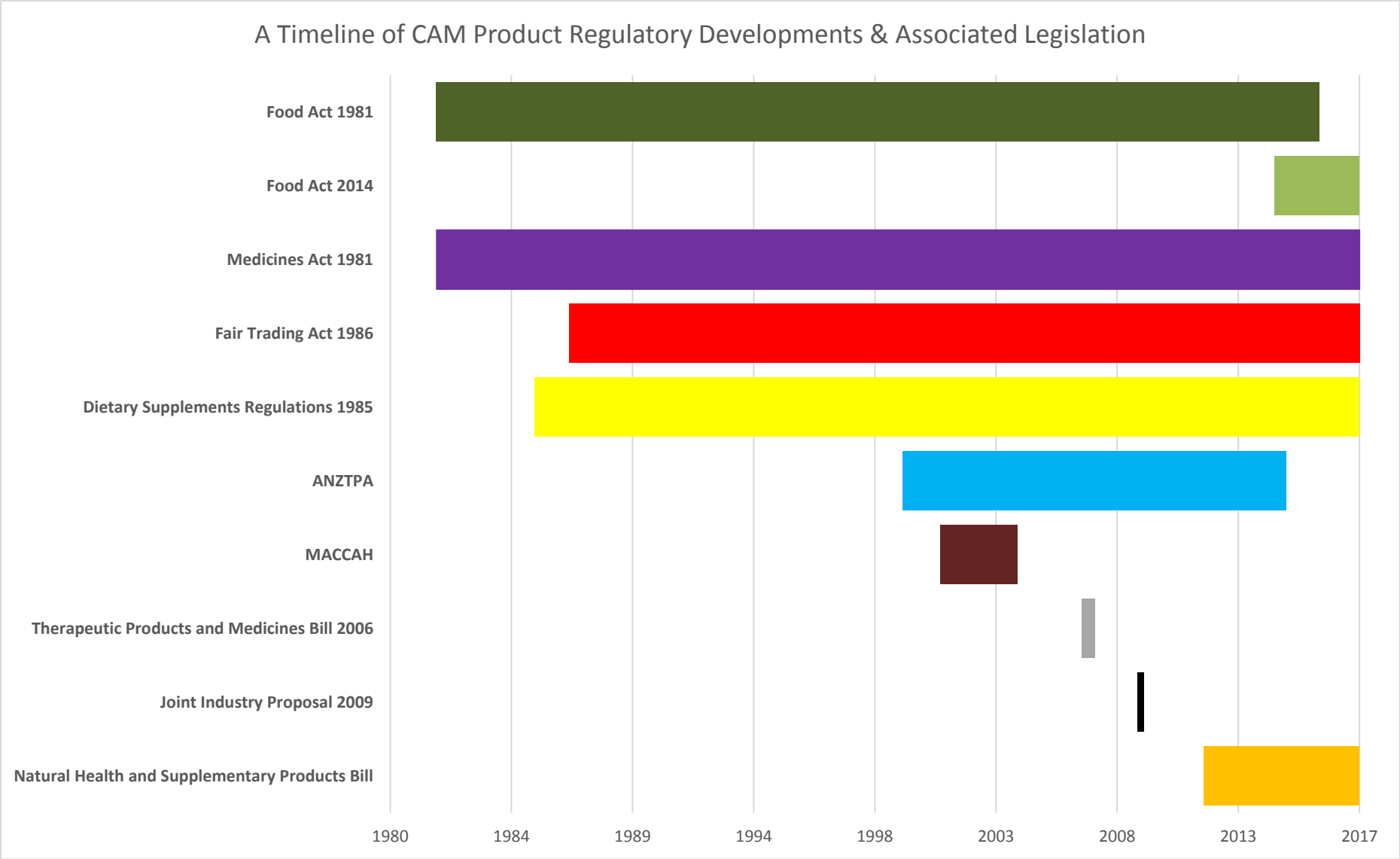

Figure 5.1: A Timeline of CAM Product Regulatory Developments & Associated Legislation

5.3 A History of CAM Product Regulation since the Dietary Supplements Regulations 1985

It has been more than thirty years since the enactment of the DSRs, and during that time, there have been multiple attempts to update the legislation and regulations around CAM products.[400] From 1999-2014, much of this drive to update NZ's regulations centred on a joint-Agency approach with Australia for the regulation of medical devices and therapeutic products, which included CAM products. However, this was a contentious issue throughout ANZTPA's lifecycle, and while its support ebbed and flowed, three proposals came and went. Despite their ultimate failure, some elements of these four key proposals are present in the NHSPB, and therefore a discussion of the history of these failed regulatory initiatives is a valuable place to start in order to understand that Bill. Figure 5.1 depicts the complexities and temporal overlap of these developments and the legislation surrounding them.

5.3.1 The Australia-New Zealand Therapeutic Products Agency (1999-2014)

The ANZTPA was a product of the late 20th century drive for a closer relationship with Australia.

The genesis of the ANZTPA can be traced to the initial Closer Economic Relations agreement between NZ and Australia in 1983.[401] Building on this, the TTMRA came into being in 1998, although this notably excluded therapeutic products from its ambit.[402] What followed was a drive by the fourth National Government[403] to establish a separate scheme for the trans-Tasman regulation of therapeutic products. This culminated in a proposal by the Government for a joint-Agency approach in 1999.[404] This proposal took shape in 2003, when the fifth Labour Government[405] signed a treaty with Australia to pursue a system of joint regulation for therapeutic products.[406]

There were four key landmarks on the road to implementation of joint regulation once the 2003 Treaty was signed. In 2004, the Ministerial Advisory Committee on Complementary and Alternative Health (MACCAH) issued their report on Complementary and Alternative Health Care in NZ.[407] The second

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[400] von Tigerstrom, above n 31, at IV; von Tigerstrom has described these regulations as being so weak as to be tantamount to deregulation.
[401] New Zealand Australia Closer Economic Relations - Trade Agreement, with Exchange of Letters [1983] NZTS 1 (1 January 1983).
[402] See further on the CER and TTMRA at 2.5.1.
[403] 1990-1999, the Bolger-Shipley Government.
[404] (12 December 2006) 636 NZPD 7087.
[405] 1999-2008, the Clark Government.
[406] Agreement between the Government of New Zealand and the Government of Australia for the Establishment of a Joint Scheme for the Regulation of Therapeutic Products (signed 10 December 2003, not yet in force).
[407] Ministerial Advisory Committee on Complementary and Alternative Health, above n 16; Although formed in 2001, the MACCAH took account of recent developments in the form of the 2003 Treaty, and tailored its recommendations to the Minister of Health, the Honourable Annette King accordingly; see further at 5.3.2.

landmark was the tabling of the Therapeutic Products and Medicines Bill[408] in Parliament in December 2006 by the Labour Government. This Bill was the NZ implementing legislation for the joint-Agency, however it suffered from a lack of support in the House, and was abandoned in 2007 before its second reading.[409] Thirdly, in June 2011 the National Government issued a 'statement of intent' alongside the Australian Government, signalling a restart to implementation of the joint-Agency approach after its four year lapse.[410] This statement set a five-year timeline for the ANZTPA's establishment, and excluded CAM products from the Agency's ambit, catalysing work on the NHSPB.[411] Finally, in 2014, a joint statement was issued by both Governments spelling an end to the ANZTPA, and leaving each country to go their separate ways with the regulation of therapeutic goods.[412]

5.3.2 The Ministerial Advisory Committee on Complementary and Alternative Health (2001-2004)

In 2001, the MACCAH was commissioned to conduct a wide-scale review of CAM health care; in particular the regulations surrounding practitioners and the safety, efficacy, benefits, and costs associated with CAM therapies, in order to facilitate the creation of guidelines for CAM health care.[413] During this process, multiple developments in this area occurred of which the Committee took account; including the enactment of the Health Practitioner Competence Assurance Act 2003, and signing of joint-Agency Treaty with Australia as previously mentioned.[414]

The Committee recommended regulation of practitioners according to the risk associated with their modalities, but there were no changes to practitioner regulation following the report.[415] Two of the Committee's recommendations were implemented, with a CAM Database to provide reliable information for consumers on the evidence surrounding CAM products and treatments ('evidence summaries'), and the establishment of a NZ unit which could facilitate the evaluation of safety and efficacy of CAM products.[416] Although initially supported by the Government, over the ensuing years neither have been successfully utilised. The CAM Database was abandoned in 2006 "…because only a small number of evidence summaries could be produced with the resources available and a change in

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[408] Therapeutic Products and Medicines Bill 2006 (103-1).
[409] Annette King "Therapeutics Products and Medicines Bill on hold" (press release, 16 July 2007); see discussion on Therapeutic Products and Medicines Bill 2006 at 5.3.3.
[410] John Key "Australia, NZ announce intention on ANZTPA" (press release, 20 June 2011).
[411] Medsafe "Australia New Zealand Therapeutic Products Agency (ANZTPA)" (28 January 2012) <www.medsafe.govt.nz>; see discussion on early history of the Natural Health and Supplementary Products Bill 2011 at 5.5.
[412] Peter Dutton and Jonathan Coleman "Joint Statement regarding ANZTPA" (joint media statement, 20 November 2014).
[413] Ministerial Advisory Committee on Complementary and Alternative Health, above n 16, at iii.
[414] See discussion above at 5.3.1.
[415] Ministerial Advisory Committee on Complementary and Alternative Health, above n 16, at 5.
[416] At 5-6.

priorities."[417] Similarly the NZ CAM unit[418] was moved between tertiary institutions for a couple of years, before quietly fading from the radar.[419] At the end of the day, few of the recommendations from the MACCAH report affected CAM regulation in NZ in a consequential way, and fewer still made their way into the Therapeutic Products and Medicines Bill.

5.3.3 The Therapeutic Products and Medicines Bill 2006 (2006-2007)

The Labour Government's Therapeutic Products and Medicines Bill 2006[420] was introduced as an omnibus Bill which was intended to be divided later in the legislative process into two distinct bills: Parts 1-5 comprising the Therapeutic Products Act 2006, and Parts 6-7 to become the MA 2006.[421] The Bill, and the joint-Agency approach sought to address "…2 key problems…" with NZ's regulation of therapeutic products; "…outdated legislation, and a regulatory capacity that is not sustainable even in the short to medium term."[422]

The Bill introduced a risk-based approach for the regulation of CAM products,[423] although the focus was on "…provid[ing] assurance about safety and quality",[424] rather than efficacy. In order to bring NZ legislation into a position where harmonisation with Australia and other countries was possible, the Bill introduced the broadest interpretation of CAM products to date, including; "…herbal remedies and medicines, traditional treatments, homeopathic remedies, and most dietary supplements."[425]

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[417] New Zealand Health Technology Assessment and New Zealand Guidelines Group "Complementary and Alternative Medicine: High quality and effective alternative medicines" (2017) <www.cam.org.nz>.
[418] Annette King "Response to MACCAH report released" (press release, 16 December 2004).
[419] The 'New Zealand Centre for Evidence-Based Research into Complementary and Alternative Medicine' was established in July 2004 at the University of Otago, but did not last long before being amalgamated into the School of Health Sciences at the University of Canterbury in 2005. Following the move, research outputs from the Centre on the safety and efficacy of CAM products have been increasingly few and far between, however on paper, the Centre appears to still exist within the College of Education, Health and Human Development at the University of Canterbury; University of Canterbury "ENZCAM: College of Education, Health and Human Development" (2017) <http://www.education.canterbury.ac.nz/healthsciences/enzcam/>.
[420] Therapeutic Products and Medicines Bill 2006 (103-1).
[421] As previously mentioned, this Bill was the NZ implementation legislation for the ANZTPA; see 5.3.1 for brief note on the place of Therapeutic Product and Medicines Bill 2006 in the context of the ANZTPA.
[422] Therapeutic Products and Medicines Bill 2006 (103-1) (explanatory note) at 3.
[423] At 3-4.
[424] At 3.
[425] At 4.

Before the Bill's first reading,[426] three issues emerged which would eventually be fatal for the Bill. The first major problem was the cost of the proposed system.[427] As with any novel regulatory system, the costs of implementing the system were likely to be substantial, although an exact figure was never provided.[428] Additionally, the long term costs for NZ were estimated at $20m per annum;[429] nearly three times Medsafe's annual budget at the time.[430] There was concern that these costs would be passed on to consumers, or would drive small CAM product players out of the market.[431] To address this, the Government negotiated a fifty-percent subsidy to the costs of regulation in order to gain the support of two minor parties and thus get the Bill passed its first reading.[432]

The second and third issues are closely related. There was substantial concern from the Māori Party that rongoā[433] was going to be adversely affected by the Bill.[434] Despite assurances from the Government that it was excluded from the legislation's ambit, as it is under the MA,[435] there remained doubt as to how long this would endure, with many projecting that this exclusion would only last until the Bill received Royal Assent.[436] In addition, the Green and Māori parties expressed concern that a joint-agency would result in Australia effectively having control of NZ's therapeutic goods regulation.[437] The Māori Party believed this Australian influence would erode protection of rongoā.[438]

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[426] Even before the Bill's introduction, issues with the Bill emerged; notably, the provisions on direct to consumer advertising. Early drafts of the Bill banned direct to consumer advertising, but the Government was required to compromise on this ban due a lack of support in the House in the lead-up to the first reading. Consequently, the Bill was amended to permit direct to consumer advertising, although assurances were made that the standards for true and balanced advertisements would be enforced. (12 December 2006) 636 NZPD 7073.
[427] At 7070.
[428] While $9 million was mentioned as the cost of the proposed new agency during the first Parliamentary debate on the Bill, it is unclear whether this refers to the costs for implementation, or a projection of ongoing costs; at 7076.
[429] Therapeutic Products and Medicines Bill 2006 (103-1) (explanatory note) at 93; the total cost of the joint-agency was estimated to be $68 million annually, with a presumption that 30% of the costs would be borne by NZ commensurate with the forecasted number of product licence holders.
[430] At 92; Medsafe's budget was $6.7 million in 2006.
[431] (12 December 2006) 636 NZPD 7070-7071.
[432] At 7076; there is no reconciliation in the Hansard of the $9 million figure quoted therein for regulation, with the $20 million figure posited in the Explanatory notes to the Bill. One possible explanation for this discrepancy is that the $9 million per annum reflects initial costs associated with setting up the joint-agency, while the $20 million per annum is the forecasted operating costs for NZ once the agency is established.
[433] Rongoā or Rongoā Māori is the all-encompassing term for traditional Māori medicine. Like many forms of traditional medicine, it is a holistic type of medicine which focuses broadly on health and wellbeing in a manner closely interwoven with Māori culture and practices. There are three elements which largely comprise rongoā; rakau rongoā, which corresponds to herbal medicine; mirimiri, which is massage or broadly manual manipulation; and karakia, which is prayer. This is evidence of indispensable role of practitioners in rongoā. See Ministry of Health, above n 21, for more information on rongoā in New Zealand.
[434] (12 December 2006) 636 NZPD 7079.
[435] At 7085-7086; Medicines Act 1981, s28.
[436] At 7079-7081.
[437] At 7077-7079.
[438] At 7080-7081.

However, the structure of the ANZTPA was such, that while Australia's size may result in it strong-arming NZ, there was in theory an equal balance of power between the two countries, as each was allotted an equal status under this system.[439]

While the Bill passed its first reading on 12 December 2006, with 61 to 60 votes,[440] the Select Committee was unable to reach an agreement to recommend the Bill to Parliament for its second reading. Coupled with the aforementioned problems and widespread public concern about access to CAM products,[441] the Bill failed to reach its second reading. In somewhat of a Catch-22 situation, the issues of a capacity deficit and outdated legislation are thus magnified by every passing year without new legislation.

It is also important to appreciate that the Australian system for the regulation of CAM products and medicines was (and remains) one of the strictest in the world,[442] and this affected the public opinion with respect to a joint-agency approach. The Therapeutic Goods Act 1989 (Cth) creates the Australian Register of Therapeutic Goods, wherein medicines or CAM products must be classified as either registered goods, or listed goods. Registration of therapeutic goods is the more onerous standard, requiring consideration of an extensive list of criteria in s25 Therapeutic Goods Act, and broadly comprising all prescription medicines and the majority of non-prescription medicines and other high risk goods.[443] The listing of therapeutic goods is a lesser regulatory burden for low risk products, whereby they are still listed on the Register, but need not prove efficacy when applying for listing,[444] nor are the claims on the label required to be vetted prior to listing, although the sponsor must hold evidence in support of the claims.[445] Listed goods must also only contain 'permissible ingredients' as stated on a white-list.[446]

5.3.4 The 'Joint Industry Natural and Traditional Health Products Bill' Proposal (2009)

In 2009, a proposal entitled the 'Natural and Traditional Health Products Bill' was drafted by a joint industry taskforce comprising a number of consumer and industry groups, heavily invested in the CAM

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[439] von Tigerstrom, above n 31, at IV. A loss, or at least lessening of sovereignty was not an entirely unfounded concern, given the structure of the Food Safety Australia New Zealand Authority wherein NZ has a voice equivalent to one Australian state; (12 December 2006) 636 NZPD 7068-7069.
[440] New Zealand Labour, New Zealand First, United Future and Progressive parties in favour, New Zealand National, Green, Māori and Act New Zealand parties against.
[441] At 7079-7081, 7083 and 7091.
[442] Ellena, above n 9.
[443] Eloise Archer and others "Regulation of complementary and alternative medicine: interplay of therapeutic goods legislation consumer law" (2013) 25(1) Bond Law Review 13, at 15.
[444] Therapeutic Goods Administration "Listed medicines" (2017) Department of Health <www.tga.gov.au>.
[445] Therapeutic Goods Act 1989 (Cth), s26A(2)(fb) and (fc).
[446] Therapeutic Goods (Permissible Ingredients) Determination No.1 of 2017 (Cth).

product market.[447] With the Therapeutic Products and Medicines Bill abandoned in 2007, the industry posited this proposal as a solution to the lack of regulation of CAM products and those involved in their import, export and manufacture.

While the Proposal is clearly biased due to nature of its drafters, it does present some issues confronting a novel CAM product regulatory system. These include the problems with classifying CAM products somewhere between food and medicines,[448] questions around how to practically implement Health Select Committee recommendations from the inquiry into the trans-Tasman agency,[449] and the omnipresent funding issues.[450] In addition, the Proposal suggests a co-regulation model between industry and government which is jointly funded by the two.[451] It notes that all CAM products should come under this form of regulation, with manufacturers operating under an approved risk-management programme, and "where appropriate, GMP",[452] with a black-list dictating the products which are prohibited.[453]

Despite the Proposal raising some pertinent issues, it was ultimately unworkable due to an absence of legal mechanisms necessary in regulation of this kind. The Proposal endeavoured to remove any oversight; exemplified in the ouster clause which prevents any "…regulations, rules or decisions that may assume such products are inherently unsafe."[454] Furthermore, there were limited penalties for a breach, with clause 23 outlining "education"[455] and "…penalties… [that] encourage compliance (i.e. 'name and shame')"[456] as the primary and secondary sanctions respectively.[457] Following the initial release of the draft proposal in 2009, the joint industry Proposal resurfaced in 2012 as a submission on the NHSPB (a Government Bill),[458] however aside from an oblique reference to its peremptory position in the summary of submissions,[459] it has otherwise largely faded away.

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[447] Natural Health Alliance *Joint Industry Natural and Traditional Health Products Bill 2009* (NZ Health Trust, online, February 2009).
[448] At 4-5.
[449] At 11-12; Health Select Committee *Inquiry into the proposal to establish a trans-Tasman agency to regulate therapeutic products* (New Zealand Parliament, online, 9 December 2003).
[450] Natural Health Alliance, above n 447, at 15.
[451] At 12.
[452] At 7 and 18-19.
[453] At 11.
[454] At 22.
[455] At cl23(a).
[456] At cl23(b).
[457] Natural Health Alliance, above n 447, at 37.
[458] Appleton Associates Limited, above n 374.
[459] Ministry of Health *The Development of a Natural Health Products Bill: Summary of Submissions* (Ministry of Health, Wellington, June 2011), at 3.

5.4 An Overview of the Natural Health and Supplementary Products Bill 2011

Simply, the Bill aimed to regulate CAM products.

To appreciate why this is necessary, the entirety of the thesis until this point should be reflected upon, in addition to a couple of general points. Regulation of CAM products is necessary to control a $1.4 billion industry,[460] and an internal market which may contain around 20,000 individual CAM products,[461] where both exporters and manufacturers are drawing upon the 'Pure NZ' or 'clean, green NZ' brand in marketing 'bioactives'.[462] As previously discussed, new legislation has been sorely needed for decades, as the DSRs fail to adequately regulate the industry, leaving NZ out of line with most other developed countries.[463]

The Bill aimed to regulate CAM products via a range of reactive mechanisms, rather than a pure risk-based approach targeted towards each product's respective risks. This includes: product licensing requirements,[464] regulation of ingredients,[465] export and manufacturing controls,[466] restrictions on the nature of products' claims,[467] labelling[468] and advertising,[469] and development of penalties in the event of a breach of any part.[470]

The Bill created a new Authority and committees, who together would have broad power and discretion with respect to application of the Bill and decision making therein. [471]

The framework for the Bill is broadly modelled on the Canadian approach in the Natural Health Product Regulations 2003,[472] which come under the umbrella of the Food and Drugs Act 1985.[473] In a

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[460] Natural Products New Zealand, above n 2, at 1.
[461] Ministry of Health, above n 3, at 1; due to the lack of information on the manufacture of CAM products in NZ, there is widespread uncertainty as to the exact number of products in the NZ market.
[462] New Zealand Trade & Enterprise "New Zealand Bioactives" (2017); Bioactives is an all-encompassing term commonly used by New Zealand Trade & Enterprise in reference to anything from dairy products through to CAM products. Its use in reference to CAM products was somewhat popularised between Ministries like NZ Trade & Enterprise and what is now Ministry of Business, Innovation and Employment (MBIE) following the release of the *New Zealand Bioactives Report 2008*, commissioned by New Zealand Trade & Enterprise and produced by L.E.K. Consulting Pty Limited.
[463] Ministry of Health, above n 3, at 5.
[464] Natural Health and Supplementary Products Bill 2011 (324-2), cls11-12 and 13-19A; see 5.6.6.
[465] At cls20-24A; see 5.6.4.
[466] At cls25-34.
[467] At cls12A-12C; see 5.6.5.
[468] At cl24.
[469] At cl12A.
[470] At cls36-40C; see 5.6.7.
[471] At cls8-10 and 43-45A; see 5.6.3.
[472] Natural Health Products Regulations (SOR/2003-196) (Canada).
[473] Food and Drugs Act 1985 (Canada).

similar way to the NHSPB, as shall be seen below, the Canadian system employs a white list and a black list in respectively permitting or prohibiting CAM products.[474] The product licencing requirements in Canada are more stringent than those proposed under the NHSPB, with a clear pre-approval process requiring extensive details on the product's ingredients, source, dose, potency, recommended uses, safety and efficacy, and labelling.[475]

5.5 The legislative history of the Natural Health and Supplementary Products Bill 2011

The NHSPB endured more than six years in the legislative process, however, it was withdrawn by the Labour-NZ First coalition Government at the beginning of the 52nd Parliament.[476] This section looks to briefly recount the history and changes to the Bill over that time.

5.5.1 The Bill's drafting (2008-2011)

Taking power in 2008, the National Party signed a memorandum of understanding with the Green Party.[477] One of the key elements of this was the development of a new Natural Health Products Bill. On 19 March 2010, a Consultation Paper was released to the public: 'The Development of a Natural Health Products Bill'.[478] The Paper set out the background[479] to the proposal and options for the regulation of CAM products.[480] The consultation period elicited about 1500 responses, of which two-thirds generally agreed with the proposal, while highlighting some changes to be included.[481]

The Bill was subsequently drafted, and a regulatory impact statement for the new legislation was released in June 2011.[482] Perhaps most telling in this statement is the acknowledged widespread uncertainty surrounding empirical data on CAM products,[483] the CAM product marketplace,[484] CAM product usage, and safety;[485] ultimately demonstrating the broader problem of an information deficit

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[474] Natural Health Products Regulations (SOR/2003-196) (Canada), at Schedules 1 and 2.
[475] At reg5. For further information on the Canadian regulation of CAM products, see Volpe, above n 373; Ellena, above n 9; Health Canada "About Natural Health Product Regulations in Canada" (8 December 2016) Health Canada <http://www.hc-sc.gc.ca>; and Health Canada "Compendium of Monographs - Natural Health Products" (08 December 2016) Health Canada <http://www.hc-sc.gc.ca>.
[476] The 52nd Parliament began on 7 November 2017, and the NHSPB was not reinstated, consequently being taken as withdrawn on 8 November 2017; New Zealand Parliament "Natural Health and Supplementary Products Bill" (8 November 2017) <www.parliament.nz>.
[477] "Memorandum of Understanding Between The New Zealand National Party and The Green Party of Aotearoa New Zealand" (8 April 2009) at 1-2.
[478] Ministry of Health *The Development of a Natural Health Products Bill: Consultation paper* (19 March 2010).
[479] At 1.
[480] At 5.
[481] At 2-3.
[482] Ministry of Health, above n 3.
[483] At 2-3.
[484] At 2.
[485] At 3-6.

around CAM products in NZ. This uncertainty was frequently highlighted by public submissions on the Bill during the Select Committee stage,[486] which questioned the veracity of assumptions upon which the Bill was premised, when there was little to no data in support of them.[487]

5.5.2 The first and second readings (2011-2013)

The Bill was introduced to Parliament on 7 September 2011, and had its first reading on 15 September.[488] The Labour opposition affirmed the Bill at its first reading, resulting in general cross-floor support for the Bill. At this time, the Bill was heralded as a cost-effective solution which reflected the allegedly low-risk status of CAM products,[489] and promoted consumer protection through regulation of labelling, health claims, and control of the ingredients in these products.[490] Inklings of concern were raised by a couple of members on issues like the ongoing Wai 262 claims,[491] international trade and best-practice,[492] and whether the costs would truly be as low as forecast.[493] Nevertheless, the Bill was still widely supported and progressed to the Health Select Committee.

The Select Committee considered 739 submissions on the Bill before returning it to Parliament on 31 October 2012.[494] The submissions were fairly polarised, from the readily anticipated submissions of CAM product manufacturers and industry groups decrying the costs and control placed on the industry, through to scientific, medical and healthcare professionals who questioned whether the Bill went far enough, suggesting that it relied on unsubstantiated assumptions about the safety of CAM products and the good-will of the industry to follow loose regulations.[495]

In a minority opinion published alongside the Select Committee report,[496] the Green Party raised some concerns.[497] These concerns addressed the restrictiveness of allowable claims,[498] the absence of a

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[486] See below at 5.5.2.
[487] For example, the dearth of data on the safety of CAM products, and therefore how they can be considered low-risk when there is no evidence of this. See further at 5.6.
[488] Natural Health and Supplementary Products Bill 2011 (324-2).
[489] (15 September 2011) 675 NZPD 21385.
[490] At 21385.
[491] See 8.3 on the WAI262 claims; (15 September 2011) 675 NZPD 21388, Dr Paul Hutchison MP, and at 21391, Te Ururoa Flavell MP.
[492] At 21388-21389, Kris Faafoi MP.
[493] At 21392, Hon Steve Chadwick MP.
[494] Natural Health and Supplementary Products Bill 2011 (324-2) (select committee report) at 15.
[495] See further discussion of submission at 5.6.
[496] Natural Health and Supplementary Products Bill 2011 (324-2) (select committee report) at 11-14.
[497] It is unclear from the Commentary on the Bill whether this minority opinion was raised by the Green Party members of the Select Committee; namely Kevin Hague and Mojo Mathers, or whether the Green Party was given the opportunity to comment on the Select Committee report in recognition of the Memorandum of Understanding, which allows greater input by the Green Party into such matters on a case by case basis.
[498] See discussion on allowable claims at 5.6.5.

completed permitted substances list,[499] and the lack of inclusion of the Treaty of Waitangi.[500] The majority of the Select Committee recommendations were uncontroversial minor amendments, although five bear noting. Firstly, the title was amended to include 'supplementary products' to reflect the broad range of products in the Bill.[501] Additional emphasis was placed on the scientific and traditional underpinnings of the Bill in cl4(d),[502] while greater limitations were added to the definition of 'Natural Health and Supplementary Product' in cl6, with the definition of 'food' including anything presented as a food,[503] and that of medicine excluding related products and medical devices.[504] The fourth recommendation was increasing the amount of detail around allowable claims and health benefit claims (HBCs), with the addition of cls12A,[505] 12B,[506] 12C,[507] and 13(2A).[508] Finally, the recommendations suggested a broader scope of products excluded from notification, and thus regulation under the Act.[509] The exclusion was to include homeopathic products, as the Committee noted "…there is no accepted scientific evidence for the effectiveness of homeopathy and therefore that health benefit claims should not be made for homeopathic products on this basis."[510]

The second reading was held on the 20 March 2013, during which a number of questions arose on pertinent matters like the pre-market notification process,[511] the black or white list approach to products,[512] the definition of a natural health and supplementary product (NHSP),[513] and the importance of scientific evidence in the health claims made on products.[514] These matters form the basis for the discussion on the content of the Bill at 5.6, for they provide a hint of some of the problems which may have arisen from the Bill. Nevertheless, the Bill was widely supported, the amendments

[499] See discussion on permitted ingredients at 5.6.4.
[500] See discussion on the absence of the Treaty of Waitangi from the NHSPB at 5.6.2 and Chapter 8.
[501] Natural Health and Supplementary Products Bill 2011 (324-2) (select committee report) at 2-3; see further at 5.6.1.
[502] At 3.
[503] At cl6(1)(c) and cl6(3).
[504] At cl6(2)(b) and (c).
[505] At cl12A, "Health benefit claims relating to named conditions".
[506] At cl12B, "Authority may determine allowable claims".
[507] At cl12C, "Named conditions".
[508] At cl13(2A), "Before completing the product notification, the product notifier must make available on an Internet site, in respect of each health benefit claim made for the product, a summary of the evidence that the product notifier relies on to support the claim."
[509] At 8 and cl13A(d).
[510] At 8.
[511] (20 March 2013) 688 NZPD 8809-8810, per Hon Simon Bridges MP.
[512] At 8809.
[513] At 8810, per Hon Maryan Street MP.
[514] At 8811-8812, per Dr Paul Hutchison MP, and at 8812-8813, per Ian Lees-Galloway MP.

made by the Health Select Committee majority were agreed to, and the Bill passed its second reading with 120-1 votes in favour.[515]

5.5.3 Subsequent process (2013-2017)

More than two years passed before any further developments took place around the NHSPB. While the 2014 general election undoubtedly slowed the process somewhat, the National Government who had introduced the Bill remained in power, and no official explanation was offered for this delay, although perhaps the Government was waiting to ascertain developments with the ANZTPA before proceeding.[516] In 2015, substantial work began on guidance documents and codes by the MoH for the practical implementation of the Bill.[517] In addition to the consultation on these documents, extensive stakeholder discussions were underway on the draft permitted substances list for the Bill. This process sparked concern from many within the industry and related fields given the nature of the list and its evolution towards a white-list.

In August 2017, when Parliament dissolved before the 2017 General Election, the Bill was very much on the back-burner of the Government's priorities, despite waiting more than four years for its third reading. Deadlines had constantly been extended for the making of the permitted substances lists and consultation on similar matters. With a change of Government following the 2017 election from a National-led Government to a Labour-NZ First Government, the Bill was withdrawn with little explanation, leaving a void for a new proposal for the regulation of CAM products in NZ.[518]

5.6 A Detailed Consideration of the Natural Health and Supplementary Products Bill 2011

This section takes a detailed look at the NHSPB, with a focus on key elements of the Bill, many of which proved contentious during its history. The section narrows in on definitions or omissions in the Bill, before turning to the administrative structure and bodies created by the NHSPB. Finally, four novel parts of the Bill are considered; permitted ingredients, allowable claims, product notification, and the costs and penalties.

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[515] At 8817-8818; ACT New Zealand were the only Party to vote against the Bill at its second reading.
[516] As mentioned at 5.3.1, ANZTPA arrangements were finally ended in November 2014.
[517] Ministry of Health *Draft Code of Manufacturing Practice* (Ministry of Health, Natural Health Products Draft Papers, November 2015); Ministry of Health *Draft Code of Manufacturing Practice Guidelines* (Ministry of Health, Natural Health Products Draft Papers, November 2015); Ministry of Health *Draft Guidelines for Natural Health Products Evidence Requirements* (Ministry of Health, Natural Health Products Draft Papers, November 2015); Ministry of Health *Proposed list of conditions about which claims can be made* (Ministry of Health, Natural Health Product Draft List, November 2015); Ministry of Health *The Regulation of Natural Health Products* (Ministry of Health, Natural Health Products Consultation document, November 2015).
[518] (8 November 2017) 725 NZPD (provisional daily) per Hon Gerry Brownlee.

5.6.1 Definitions

Definition of 'dietary supplement'

One of the first definitions seen in the NHSPB is that of 'dietary supplement'. The wording of the definition is nearly identical to that in reg2A(4)-(6) DSRs,[519] and therefore would appear to be included to ensure a smooth transition from 'DSs' to 'natural health and supplementary products' as the legislation comes into force.

Definition of 'natural health and supplementary product'

The term 'supplementary' was added to the definition and name of the Bill by the Select Committee, to broaden its scope and the products which were included in its regulation. As such, cl6 defined 'natural health and supplementary product'.[520] There are a plethora of important aspects to this definition. Firstly, it is interesting to note that NHSPs are defined first by their purpose at cl6(1)(a), and then by exactly what they are at cl6(1)(b). Clauses 6(1)(c) and 6(2) then go one to define NHSPs

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[519] Natural Health and Supplementary Products Bill 2011 (324-2), cl5 'dietary supplement': "dietary supplement means a product that is –

(a) sold in a controlled dosage form as a liquid, powder, or tablet (which might be described on the label as a cachet, capsule, lozenge, or pastille instead of as a tablet); and
(b) intended to be ingested orally; and
(c) intended to supplement the amount of the amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin normally derived from food"

[520] At cl6 "Definition of natural health and supplementary product

(1) Natural health and supplementary product means, subject to subsection (2), any product that –
    (a) is, or appears to be, manufactured –
        (i) for human use; and
        (ii) for the primary purpose of bringing about a health benefit to the person who uses the product; and
    (b) contains only permitted ingredients unless –
        (i) section 22(2)(b)(i) applies; or
        (ii) the product is a dietary supplement; and
    (c) is not, or is not presented as, a food.
(2) Natural health and supplementary product does not include –
    (a) any medicine that –
        (i) the Minister has, under section 20 or 23 of the Medicines Act 1981, given consent to its distribution; or
        (ii) the Minister is, under section 20(7) of that Act, deemed to have given consent to its distribution; or
        (iii) the Director-General, has under section 24 of that Act, given consent to its distribution:
    (b) any related product that the Minister has, under section 20 and 96 of the Medicines Act 1981, given consent to its distribution:
    (c) any medical device that is the subject of a declaration under regulation 6 of the Medicines (Database of Medical Devices) Regulations 2003.
(3) In subsection (1), food means anything that is ordinarily used or represented for use as food or drink for human beings.

by what they are not; namely that they are neither foods nor medicines. It is worth noting the NZ Law Society's submission on the Bill, which raised a question on the overlap between the definition of 'natural health product' and 'food' in the Bill, which would cause many NHSPs to be "…unintentionally excluded from the Bill."[521] The Select Committee saw the same issues, and substantially changed it to what is seen in the final version of the Bill.[522] The Select Committee recommended that the definitions of food in cl6, and in the Food Bill (now FA 2014) be consistent to reflect the relationship between the two pieces of legislation.[523]

In addition to defining the products it covered by their purpose and 'permitted ingredients', this definition of NHSP represents a monumental change from the DSRs, in that this definition clearly states that these products are neither foods, nor medicines. This issue was directly addressed by the Select Committee, where it noted the difficulty between distinguishing foods, medicines and NHSPs, but also their desire to have a clear divide between them; for example, herbal tea as a food, and honey as a NHSP, if that were its purpose.[524] The emphasis on the purpose of the product as a defining characteristic to its classification substantially improves the coherence and workability of the

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[521] New Zealand Law Society "Submission to the Health Committee on the Natural Health Products Bill 2011" (2012) at [5].

[522] Formerly, cl6 read: "Definition of natural health product

(1) In this Act, unless the context otherwise requires, a natural health product means a product—
    (a) that is intended by the sponsor of the product—
        (i) to be administered to a human being; and
        (ii) to bring about a health benefit to the person to whom the product is administered; and
        (iii) to be administered by any of the methods specified in subsection (2); and
        (iv) not to be administered by any of the methods specified in subsection (3); and
    (b) that, subject to section 22(2)(b)(i), contains only natural health product ingredients; and
    (c) that does not contain any prohibited ingredient; and
    (d) that is not—
        (i) a food; or
        (ii) a prescription medicine or pharmacy-only medicine as those terms are defined in the Medicines Act 1981; or
        (iii) a controlled drug within the meaning of the Misuse of Drugs Act 1975.
(2) The methods of administration referred to in subsection (1)(a)(iii) are the following:
    (a) oral ingestion:
    (b) application to the skin, scalp, or nails:
    (c) application to the teeth, throat, anal canal, or vagina:
    (d) application to the mucosa of the mouth or nose.
(3) The methods of administration referred to in subsection (1)(a)(iv) are the following:
    (a) injection or parenteral infusion:
    (b) application to the eye:
    (c) application in the ear."

Now cl6 reads as at footnote 520. The amendments to prevent overlap between food, medicines and NHSPs can be seen in subs(2) and (3) in the new version at footnote 520.

[523] Natural Health and Supplementary Products Bill 2011 (324-2) (select committee report), at 4.

[524] At 4.

legislative framework around CAM products, and would have alleviated much of the confusion discussed at 4.4 above.

Lack of definition of 'natural'

Despite the added clarity to the definition of NHSPB, the unrestrained and undefined use of the polyseme 'natural' in the Bill remained a problem. The term was neither defined in the Bill, nor in the Health Committee Commentary preceding it. However, a number of professional submissions addressed the problems with the use of this term. This is best summarised by the Chief Science Advisor to the Prime Minister, Professor Sir Peter Gluckman, who noted in his submission that; "The use of 'natural' draws on the naturalistic fallacy that what is found in nature is somehow better – even though many 'natural products' are highly toxic."[525] Both the Royal Australasian College of Physicians[526] and the NZ Medical Association put forward a similar position, with the latter noting that 'natural' indicated to consumers that the product would do no harm when this was not the case, and called for the Bill to acknowledge that natural products were not, by nature, low risk.[527]

5.6.2 The scope of the Bill and omissions

Two further definitional matters require addressing. Firstly, it is important to note that homeopathic products were not mentioned by name in the Bill, but were excluded from its scope by cl13A, which noted that product notification "…does not apply to… (d) any natural health and supplementary product in which the active ingredient to be administered is in a concentration not more than 20 parts per million.".[528] This reflects a deliberate decision not to regulate these products under this system due to the quantities of active ingredient being too small to measure, coupled with a lack of scientific evidence such that HBCs should not be allowed to be made for homeopathic products.[529]

The other matter to briefly touch upon is that of traditional medicine. Like homeopathy, traditional medicine was barely mentioned in the NHSPB, although in contradistinction to homeopathy's exclusion, it is likely that the inclusion of TM is largely implicit in the undefined term 'natural'. What is important is that dispensing of CAM products via a practitioner is not regulated under the Bill, so the practise of rongoā will not be affected by the Bill. However, were a supplier to commercially

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[525] Professor Sir Peter Gluckman, above n 6, at 1.
[526] The Royal Australasian College of Physicians "Submission to the Health Committee on the Natural Health Products Bill 2011" (February 2012) at 1.
[527] New Zealand Medical Association "Submission to the Health Committee on the Natural Health Products Bill 2011" (2012) at 3.
[528] Natural Health and Supplementary Products Bill 2011 (324-2), cl13A(d).
[529] At (select committee report), at 8.

produce traditional medicines, they would be subject to the same requirements as any other producer of NHSP under the Bill. While the Green Party sought to have recognition for the principles of the Treaty of Waitangi included in the Act, this view was not supported by the majority of the Select Committee, although no justification is offered for this.[530]

5.6.3 The Authority, its subordinates and its ambit

The power given to the Authority and Advisory Committee would have been broad under the Bill, ranging from administrative,[531] to oversight and regulation.[532]

The NHSP Regulatory Authority was first noted under cl5,[533] and officially established under cl8[534] under the control of the Director-General of Health, who is answerable to the Minister of Health. Also established is the NHSP Advisory Committee, which would have comprised no more than eight members, functioning under terms of reference drafted by the Authority,[535] and offering expert advice to the Authority.[536] It did not appear that the Authority was required to accept this advice. The only body which had been appointed to carry out work on the NHSP regulations was the Permitted Substances List subcommittee, which had a concerning composition. The subcommittee comprised 18 people, 11 of whom currently work, or have worked in the CAM product industry. Of these 11, eight own CAM product companies or CAM practices, while another two work for some of the biggest CAM product manufacturers in NZ. The remaining seven members consisted of a lawyer, four

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[530] At 14; the Green Party minority opinion is presented without comment from the majority of the Select Committee. As such, there is no justification or comment on why the Committee chose not to include any reference in the Bill to the Treaty of Waitangi. The Green Party opinion on the Treaty is as follows:
"Recognition of Te Tiriti
The Green Party is committed to legislation that honours Te Tiriti and ensures Māori participation in decision-making processes that affect them. Any system that will potentially regulate Māori taonga (such as the traditional use of plants) needs to be administered in a way that is consistent with the Treaty. While the bill exempts products made on a 1-1 basis, such as occurs with Rongoā, from notification, it still has the potential to affect the use of traditional plants. Our desired addition to the bill is to insert a clause that states, 'In achieving the purpose of this Act, all persons exercising functions and powers under it shall honour the articles of Te Tiriti o Waitangi.'"

[531] Natural Health and Supplementary Products Bill 2011 (324-2), cls12B, 20, 21 and 11; largely permitting claims on products and keeping a variety of lists updated, from the permitted to prohibited substances lists and a list of NHSPs.

[532] At cls15, 31, 35, 34, and 44; this includes auditing product notifications and manufacturers, prescribing fees and if necessary, taking remediating measures like revoking licences or issuing a recall of products.

[533] At cl5, 'Authority' means the Natural Health and Supplementary Products Regulatory Authority established under section 8.

[534] At cl8; "Natural Health and Supplementary Products Regulatory Authority
(1) This section establishes the Natural Health and Supplementary Products Regulatory Authority.
(2) The Authority is the Director-General of Health.
(3) The office of the Authority must be administered by the Ministry of Health."

[535] At cl10(5).

[536] At cl10.

scientists of varying disciplines, and two medical professionals (both of whom are also actively involved in the CAM product industry). This extremely close relationship to the industry in a committee charged with determining what substances were to be permitted under the new Act raised substantial concerns for the perceived impartiality of the committee.

5.6.4 Permitted & prohibited ingredients

The Bill was quiet around permitted ingredients and the list, aside from regularly mentioning it as one of the defining features of NHSPs. Clause 20 sets out the criteria for inclusion on the permitted ingredients list, which must be published online,[537] with any restrictions on product use included in this listing.[538] The Authority may designate any product in Schedule 1[539] as a permitted ingredient,[540] and may also perform safety testing on any such product.[541] There were three criteria for listing permitted ingredients which the Authority must consider:[542] other authorities' use or restrictions on the product,[543] recognition of the substance in TM or pharmacopoeiae,[544] and any other matters they deem relevant.[545] Alongside these permitted ingredients at cl20, is a prohibited ingredients clause.[546] This was nearly identical to that specified for permitted ingredients, but instead used the procedure for banning certain harmful products.

What was concerning about the permitted substances list was the presence of chemicals which are well-recognised as being harmful.[547] Two examples illustrate this point. The first is the colourant 'Brilliant Black';[548] widely banned, most notably in the USA.[549] Brilliant Black was included on the

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[537] At cls20(4)-(5).
[538] At cls20(2) and (4).
[539] At Schedule 1; Schedule 1 NHSPB provides a very general list on 'Suitable substances', which in addition to many of those specifically contained in the DSRs, adds a number of more general classes or substances, including, strangely enough, 'synthetic equivalents' of many of the 'natural' products.
[540] At cl20(1).
[541] At cl20(3)(a).
[542] At cl20(3)(b).
[543] At cl20(3)(b)(i).
[544] At cl20(3)(b)(ii).
[545] At cl20(3)(b)(iii).
[546] At cl21.
[547] In addition to the two examples which follow, other colourants, fragrances and artificial sweeteners present on the permitted substances list include a number of cyclohexanol compounds, which are toxic at high doses, and sweeteners aspartame, alitame and neotame. Guy Hatchard "Suspected Toxic Additives to be permitted by Medsafe under the NHP Bill" (online, The New Zealand Journal of Natural Medicine, 3 October 2016); while the veracity of comments under 'Toxicity' in this document has not been corroborated and is not relied upon, the list of compounds which are included on the permitted substances list and show at least some evidence of toxicity is accurate.
[548] Brilliant Black, Black BN, E151.
[549] The Feingold Association of the United States "List of Colorants" (2017) online <http://www.feingold.org/Research/PDFstudies/List-of-Colorants.pdf>, at 13.

permitted substances list,[550] despite evidence of allergic reactions and exacerbation of some conditions.[551] Similarly, the colouring agent Tartrazine[552] was set to be included on the permitted substances list.[553] A Southampton study showed Tartrazine to affect hyperactivity and cause impulsive behaviour in children.[554] These two examples pose serious questions about the permitted substances list, when products whose only purpose was to colour CAM products are included on the list, despite strong evidence of their risk, and when international authorities put restrictions on their use.[555]

Due to concern during and after the Select Committee stage that there was no permitted ingredients list, and thus no certainty as to the scope of the Bill, the MoH appointed the aforementioned subcommittee to consider product applications following the second reading. As of March 2017, the permitted substances list contained nearly 6,200 substances which have received approval, while the corresponding prohibited substances list has only 155 products on it.[556] While the list was voluminous, stakeholders claimed that in practice, it should contain more than twice that number of products, and this was cited as one of the major problems of the legislative scheme.[557] As of April 2017, the period for free submissions was closed, with a user-pays process to be implemented if the NHSPB had passed into law.

The permitted and prohibited substances lists are examples of white and black-lists respectively. Canada is the only other major country which operates black and white lists simultaneously, and while this appears to have functioned relatively smoothly there, it is difficult to predict its success in the distinct proposal of the NHSPB. It is likely that this system will be costly, and have a high administrative burden due to continual updates and reviews of these lists. While this approach appears to have been

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[550] Ministry of Health "Permitted Substance Search" (May 2017) <http://www.medsafe.govt.nz/regulatory/PILSearch.asp>, 'Brilliant black BN'.

[551] Panel on Food Additives and Nutrient Sources added to Food "Scientific Opinion on the re-evaluation of Brilliant Black BN (E 151) as a food additive" (2010) 8(4) European Food Safety Authority Journal 1540; while this paper notes the fact that sensitivity to food additives in asthma and other patients is uncommon, the point this seeks to illustrate is that there is an ascertainable risk associated with Brilliant Black, which when balanced against the non-existent benefit, is unacceptable.

[552] Tartrazine, E102.

[553] Ministry of Health, above n 550, 'tartrazine'.

[554] Donna McCann and others "Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomised, double-blinded, placebo-controlled trial" (2007) 370(9598) The Lancet 1560.

[555] The Authority, and for the purposes of cl20, the Committee, *must* have regard for "whether a recognised authority permits the use of the substance in a similar product and, if so, whether it imposes any restrictions on the use of the substance" Natural Health and Supplementary Products Bill 2011 (324-2) cl20(3)(b)(i). The Feingold Association of the United States, above n 549.

[556] 274 products were pending as of 30 March 2017; Ministry of Health, above n 550.

[557] Natural Health Alliance "Natural Health Products Bill and Regulations: Frequently Asked Questions" (2017) <www.naturalhealthalliance.co.nz/>; Ministry of Health, above n 3, at 1.

incorporated for the dual purposes of simplifying the approval process and adopting some vestige of a risk-based system, it lacks stakeholder support, and already appears unwieldy, costly and ineffective, where other options could viably achieve the same or greater benefits with a much lower financial and administrative burden.[558]

5.6.5 Permitted Conditions and Allowable Claims

There are two levels to the new HBCs under the NHSPB; the claims themselves, and the subset of allowable claims. Before highlighting the distinction, it is worth briefly considering how HBCs differ from TCs.

HBCs are first alluded to in the principles of the Bill as one of the defining features of the new legislation.[559] This is because one of the key goals of the Bill was to address the plethora of TCs which were not permitted under the old legislation, and make room for trusted and beneficial claims on the packaging which would aid consumer decision making, while not misleading consumers. As such, the idea of HBCs which were supported by scientific or traditional evidence was borne. While medical and scientific professionals were dismayed by the presence of 'traditional evidence' alongside scientific evidence as sufficient to support a claim,[560] this was included largely for practical reasons, for without such a provision, it is unlikely the Bill would have support of a large portion of the CAM product industry.

The Bill went on to define a 'health benefit' as being one or more of five distinct benefits.[561] Whether it is intentional or not, it is interesting to see that the various health benefits contain no mention of prophylactic effect, which is commonly regarded as the purview of CAM products. While it is possible to read this into the wording of some of the benefits, the fact that there is no direct allowance for preventing contraction of a disease, infection or condition may be indicative of a more restrictive approach to the claims on CAM products. Broadly, HBCs are distinct from the TCs prohibited by reg11 DSRs, except for sub-cl(d), and to some extent sub-cl(e). Nevertheless, in general, HBCs are envisioned

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[558] See the black-list approach proposed in Chapter 12.

[559] Natural Health and Supplementary Products Bill 2011 (324-2) cl4(d); "that health benefit claims made for natural health and supplementary products should be supported by scientific or traditional evidence."

[560] For example, Professor Sir Peter Gluckman, above n 6, at 2.

[561] Natural Health and Supplementary Products Bill 2011 (324-2), at cl5 'health benefit': "health benefit means any 1 of the following benefits:

(a) the maintenance or promotion of health or wellness:
(b) nutritional support:
(c) vitamin or mineral supplementation:
(d) affecting or maintaining the structure or function of the body:
(e) relief of symptoms"

to sit beneath TCs on a spectrum, be supported by evidence of a scientific or traditional kind, and at the end of the day, remain fairly general in nature. The potential for overlap of HBCs with TCs in the MA is recognised to some extent in the Select Committee's report, which notes the fact that high level HBCs will require the product to be listed as a medicine.[562]

The sub-group of allowable claims comes under HBCs, but concerns claims that a NHSP will treat a named condition. They are defined as such in cl5 NHSPB, with direction to cl12B which elucidates the authority's role in making such claims 'allowable'.[563] Clause 12A details the operation of HBCs which relate to named conditions and cl12C defines 'named conditions' in the context of allowable claims. Simply, allowable claims are HBCs which have been vetted through the notification process, and relate either to a pre-established condition about which a claim may be made,[564] or else are made on application by a person to the Authority with the support of evidence.[565] A named condition is specified by cl12C to be a "…disease, disorder, condition, ailment, or defect that is listed or described in the International Statistical Classification of Diseases and Related Health Problems", as published by the World Health Organisation.[566] Since the Select Committee stage of the Bill, preliminary work has been underway to develop a proposed list of condition about which claims can be made.[567] Alarmingly, this list contains a range of unexpected conditions for which claims will be allowed to be made, including a considerable number for which there are no successful medical cures currently, like Alzheimer's disease and arthritis, or more concerningly, for diseases for which there are very simple medical treatments, like diabetes. The concern around this is two-fold. For diseases with simple medical cures or treatments, the issue is that people will not seek competent medical attention, and consequently infect others or become seriously unwell without proper care. Conversely, where there are no medical cures for diseases like those listed above, people may take false hope in NHSPs which claim to be akin to 'miracle cures', at best, merely misleading patients, but at worst, causing them to neglect treatments which would otherwise alleviate symptoms and enhance quality of life for a substantial period.[568] While the consequences of HBCs for named conditions will be seen in due

[562] At (select committee report), at 7.
[563] At cl5 'allowable claim': "allowable claim means any health benefit claim that the authority has, under section 12B(1), determined may related to a named condition"
[564] At cl12A(1).
[565] At cl12B.
[566] At cl12C.
[567] Ministry of Health, above n 517.
[568] Type 2 diabetes is an example of this, where there are tried and treated medicines which work for keeping the condition in check, which work extremely well. The concern is that people instead take a CAM product, replacing their medicine with an untested remedy which might lead to a worsening of their condition.

course, it is hoped that the Authority will monitor their use, and not allow wide-scale misappropriation of allowable claims.

5.6.6 Product Notification

In the first reading of the Bill, there was no doubt that what was being discussed was a self-notification scheme, whereby the sponsor (or product notifier as the Bill now calls them) would provide all the pertinent information to the Authority, and could then go on and sell their product. However, at the time of the second reading there was an inkling of change in the air, which became apparent at the end of the Hon Simon Bridges MP's speech on the Bill.[569] In his speech, he noted that there had been concern of a change from a self-notification scheme to a pre-approval scheme; concern which he summarily dismissed.[570]

Nevertheless, this issue is worth considering. Following the Select Committee amendments to the Bill, there was certainly an altered hue to the Bill. On the face of it, the Bill still operates on a self-notification scheme, as seen in cl13, where the product notifier must merely submit the information before beginning to sell their product. However, at the same time, cl15 gives the Authority the power to audit these product notifications in any manner which is appropriate with the principles of the Act, a section which certainly opens scope for the authority to delay the marketing of this product if it deemed the product were not notified correctly.[571] Similarly, the Health Committee rewrote cl16, and added 16A and 16B, which deal more extensively with grounds for suspension, the effect of suspension, and cancellation of product notification respectively. Finally, the prohibition on HBCs relating to named conditions as previously discussed under cl12A and cl12B could also be seen to be a check on the self-notification process.

While the scheme remained largely a self-notification system, substantial uncertainty existed as to its practical implementation, which could have erred towards a pre-approval scheme if the Authority were to exercise its power in this manner. Although a minor point, this issues was indicative of the uncertainty around the functioning of the NHSPB.

5.6.7 The Costs and Penalties

There was little information available on the costs of the proposed system prior to the Bill's withdrawal, although the intention appeared to be that the scheme was jointly funded by industry and government. While it is not particularly beneficial to say much on the enforcement measures in

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[569] (20 March 2013) 688 NZPD 8808.
[570] At 8810.
[571] Natural Health and Supplementary Products Bill 2011 (324-2) cl15(2).

the Bill without context for their use, it is worth noting that the Bill increased penalties and offences substantially from the DSRs, with imprisonment available for offences involving deception or endangerment of human health, and fines for an array of offences of up to $250,000 for a body corporate, or $50,000 for an individual.[572]

5.7 Positive Developments & Pitfalls of Natural Health and Supplementary Products Bill

Finally, this section briefly considers two noteworthy developments in the NHSPB, as well as two major problems which the Bill does not address.

The first development was the publicly accessible register of CAM products.[573] This would provide consumers with basic information on a product and enables consumer and industry buy-in to ensure unregistered products are not on the market. Furthermore, this register would have made Government-mandated recall a simple procedure, in contrast to the Pan Pharmaceuticals situation, thus resolving one of the problems, as discussed at 4.5.1.

Another positive development in the NHSPB was the scheme which has been present in medicines regulations for years: that of adverse event reporting. Given how little work is involved in such a system, it is surprising that a reporting mechanism has not yet been implemented by government or industry. In addition, there is no good argument for the industry to not buy into such a scheme, given that according to their assertions, it should show nothing if the products are as safe as they claim. Nevertheless, the inclusion of cl17 on 'adverse reaction notification' feels like something of a pyrrhic victory, given the reaction must be 'serious'. A serious adverse reaction is defined at cl17(2), which lists criteria of hospitalisation, death, disability congenital abnormality or allergic reaction as the standard for requiring reporting.[574] While the inclusion of any adverse event reporting was a step in the right direction, this is a pitifully small step, given the high standard of adverse reaction required before the product notifier must alert the authority. By comparison, adverse event reporting for medicines is a much more thorough affair with a lower standard required for reporting than proposed in the NHSPB, with health professionals being required to report adverse reactions to medicines, alongside a mechanism for public reporting as well. This is orchestrated through the dedicated Centre

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[572] At cls36(3), 40(4) and (5).
[573] At cl11.
[574] At cl17(2): "In this section, serious adverse reaction means any reaction that –
(a) results in hospitalisation, or prolongs any existing hospitalisation:
(b) is life-threatening or fatal:
(c) results in disability or incapacity or requires intervention to prevent permanent disability or incapacity:
(d) results in any congenital abnormality:
(e) is an allergic reaction.

for Adverse Reactions Monitoring (CARM) wherein a substantial amount of information on the adverse event and additional medical information on the affected individual is collected and compiled in the CARM database.

Sadly, multiple problems still plagued the NHSPB. One such problem was the absence of any efficacy considerations. The Bill carefully avoided dealing with the issue of efficacy when considering the claims which could have been made on the products. While they require scientific evidence for the claims, the parallel allowance for traditional evidence effectively renders the scientific requirement moot, for if no scientific evidence exists, it should not prove difficult for a product notifier to find some claim of traditional usage from one of the 11 currently approved pharmacopoeiae at Schedule 2 NSHPB. This is out of step with international practice, where there is an increasing drive to considering integrative health and looking at ways to merge CAM products and modalities into more traditional Western healthcare models.

In this vein, the NHSPB missed the mark on a key reason for changing and updating the legislation: the issue of capacity. The largest benefit of a trans-Tasman regulation, despite its problems was the fact that together, Australia and NZ could handle the regulation of these products, where individually, neither had this capacity. While this was clear to both legislators and commentators in the early 2000s when this proposal was on the table, this new legislation makes little provision for handling the huge capacity issue when NZ attempts to regulate alone.[575]

5.8 Conclusion

Beginning with a principled consideration of some of the key issues in CAM product regulation, this Chapter reviewed the previous 30-years of CAM product regulation in NZ since the DSRs, and then focused on the most recent proposal before Parliament; the NHSPB. An overview of the Bill, coupled with its lengthy passage through Parliament emphasised some of the problems with a new regulatory scheme. While the ensuing detailed consideration of the Bill highlighted some of the positive developments arising from the Bill, there are still a significant number of issues with some of the mechanisms which the Bill intended to employ in the regulation of CAM products in NZ.

The NHSPB was far from perfect. While there is no doubt it was an improvement on the status quo, the milestones in the Bill are tempered by the number of aforementioned matters it either does not consider, or insufficiently addresses. With the Bill withdrawn from Parliament, perhaps due in part to

[575] See proposal for a novel regulatory system in Chapter 12.

public murmurings of discontent from the new Labour Government's coalition partner,[576] it will be necessary to look ahead, and consider new proposals for regulation of CAM products in NZ.[577]

[576] Winston Peters "Scrap Natural Health Products Bill" (press release, 17 May 2017).
[577] See Chapter 12.

6 Case Study: Miracle Mineral Solution

6.1 Introduction

The previous four chapters have considered specific legislation and the complex issues relating to the classification and regulation of CAM products. Before turning to more general legislative approaches to CAM product regulation,[578] it is worth briefly considering a case study which analyses the application of the food, medicine and CAM product regulations to a contentious product sold in NZ: Miracle Mineral Solution (MMS).[579] This Chapter will consider the product itself, as well as the marketing material associated with the product, before turning to an application of the earlier chapters' material to determine whether MMS is best considered a food, medicine or CAM product. Finally, the case study will turn to the remedies or enforcement which may be available under the applicable legislation, at the same time using relevant cases to theorise about possible penalties.

6.2 Background

6.2.1 A brief history of MMS

MMS was developed by former gold prospector, Jim Humble, after spending time in South America in the 1990s.[580] While neither a doctor nor a scientist, Humble created a solution from water and sodium chlorite, which he proclaimed to be an effective treatment for malaria.[581] In order to disseminate this product and associated ideology, Humble established the 'Genesis II Church of Health and Healing' based in the Dominican Republic.[582]

In the late 2000s, MMS sprang to global attention, largely due to the combination of diverse medical claims, coupled with the very real risk posed by the product. MMS does not limit itself to claims of curing malaria,[583] but has publicised its efficacy at remedying problems like toothache,[584] heavy metal

[578] See Part II: General Legislation & New Approaches.
[579] Also known as Miracle Mineral Supplement or Master Mineral Solution.
[580] Laura Donnelly and Justin Stoneman "The fake cancer cure conference the 'healers' tried to keep secret" *The Telegraph* (online ed, United Kingdom, 25 May 2015).
[581] Katherine Smith "Jim Humble MMS seminar in NZ" (9 September 2014) The New Zealand Journal of Natural Medicine, online ed. <http://www.naturalmedicine.net.nz/infections/jim-humble-mms-seminar-in-nz/>.
[582] This served the additional purpose of avoiding interference by what he labels 'Illuminati-controlled' governments; Jim V. Humble *The Master Mineral Solution of the Third Millennium* (Jim Humble, Nevada, 2011), at 238; Martin Robbins "The man who encourages the sick and dying to drink industrial bleach" *The Guardian* (online ed, United Kingdom, 15 September 2010).
[583] Humble, above n 582, at 28.
[584] At 29.

poisoning,[585] HIV,[586] all kinds of cancer,[587] and autism,[588] to name only a few. Such claims, coupled with numerous instances of adverse event reporting have caused the USA,[589] Canada,[590] the United Kingdom (UK),[591] Australia,[592] and NZ,[593] amongst other countries, to issue statements deterring consumers from purchasing and using MMS. Many of these countries have also taken steps to warn,[594] or take legal action,[595] against manufacturers or suppliers of the product because of the TCs and unsubstantiated medical representations made by MMS. Nevertheless, MMS is still widely available online in many countries, with a NZ based supplier being one key distributor of the products.

6.2.2 What is MMS?

The name 'miracle mineral solution' is itself indicative of the controversy which accompanies MMS. Sold as 'Water Purification Solution 1' (WPS1) in NZ,[596] this product contains 28% sodium chlorite,[597] and is sold with a 5% hydrochloric acid activator. In addition to the MMS product, there are newer products; MMS2 and CDS, which slightly alter the dosage or constituents.

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[585] At 23.
[586] At 27.
[587] At 27.
[588] Guy Lynn and Ed Davey "'Miracle autism cure' seller exposed by BBC investigation" *BBC News* (online ed, London, 11 June 2015); Todd Drezner "The Curious Case of Autism and MMS" *Huffington Post* (online ed, United States, 14 June 2012).
[589] Food and Drug Administration "Consumer Updates > 'Miracle' Treatment Turns into Potent Bleach" (1 October 2010) <https://www.fda.gov/ForConsumers/ConsumerUpdates/ucm228052.htm>.
[590] Health Canada "Miracle Mineral Solution: Ingesting bleach-like chemical dangerous to health" (26 March 2015) <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2015/52719a-eng.php>; Lisa Ellenwood and Lisa Mayor "Diluted bleach mixture touted as 'miracle cure' despite Health Canada warnings, the fifth estate finds" *CBC News* (online ed, Canada, 4 March 2016).
[591] Letter from Liz McNulty, (Head of Incident Response, Food Standards Agency) to Heads of Environmental Health Services (England) Miracle Mineral Solution (MMS) (24 September 2010); David Connett "Autism: Potentially lethal bleach 'cure' feared to have spread to Britain" *The Independent* (online ed, United Kingdom, 22 November 2015).
[592] Therapeutic Goods Administration "Miracle Mineral Solution (MMS)" (13 November 2014) <https://www.tga.gov.au/alert/miracle-mineral-solution-mms>.
[593] Medsafe "Medsafe warns consumers not to take Miracle Mineral Solution" (press release, 8 October 2010).
[594] At 1; Tom Minear "Genesis II Church of Health and Healing's 'Miracle Mineral Solution' slammed by AMA as 'snake oil'" *Herald Sun* (online ed, Melbourne, 3 November 2014); Erik Jensen "Deadly chemical being sold as miracle cure" *The Sydney Morning Herald* (online ed, Sydney, 9 January 2010).
[595] United States Department of Justice "May 28, 2015: Seller of 'Miracle Mineral Solution' Convicted for Marketing Toxic Chemical as a Miracle Cure" (press release, 28 May 2015); United States Department of Justice "October 28, 2015: Seller of 'Miracle Mineral Solution' Sentenced to Prison for Marketing Toxic Chemical as Miracle Cure" (press release, 28 October 2015); Health Canada "Health Canada seizes dangerous health products from online retailer" (18 October 2014) <http://healthycanadians.gc.ca/recall-alert-rappel-avis/hc-sc/2014/41859a-eng.php>
[596] MMS products are sold through the New Zealand based website; NZ Water Purifier Ltd "NZ Water Purifier Ltd" (2016) <http://www.nzwaterpurifier.com/>.
[597] $NaClO_2$

$$5NaClO_2 + 4HCl \rightarrow 4ClO_2 + 5NaCl + 2H_2O$$

Equation 6.1: Balanced Chemical Equation for the reaction of sodium chlorite with hydrochloric acid to make chlorine dioxide (chlorite), salt and water

The activated sodium chlorite, or chlorine dioxide, as it is commonly referred to in MMS material, is extremely soluble in water, where it forms chlorite ions,[598] as seen in Equation 6.1. Chlorine dioxide, or chlorite, is commonly used as a bleach and disinfectant in water treatment due to its reactivity and toxicity. In the same way that it effectively kills bacteria and viruses, it can be extremely harmful to humans, resulting in most health authorities setting restrictions on the allowable levels in water. NZ's maximum acceptable value for chlorite is 0.8 mg/L.[599] For comparison, the WPS1 MMS product sold in NZ contains 280,000 mg/L sodium chlorite,[600] which corresponds to 208,840 mg/L chlorite.[601] The MMS website contains various dilutions of the WPS1 product depending on the ailment to be treated, which reduces the concentration. Taking one of the lowest doses of six drops per day for 'maintenance'[602] will still give a dose of 280 mg/L sodium chlorite,[603] or 208 mg/L chlorite;[604] certainly enough to cause serious toxicity.

Sodium chlorite, or chlorine dioxide, is acutely toxic to humans. Side effects include nausea, vomiting, diarrhoea, and in some cases, kidney failure or methemoglobinemia[605] some of which can result in death.[606] MMS information notes these symptoms as being indicative of the product working, albeit

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[598] ClO_2^-

[599] Ministry for the Environment *Draft users' guide: National Environmental Standard for Sources of Human Drinking Water* (online ed, Wellington, May 2009), Appendix 6, Table 2.2.

[600] NZ Water Purifier Ltd "NZ Water Purifier Ltd: Products" (2017) <https://nzwaterpurifier.com/index.cfm?fact=product>; WPS1 is 28% $NaClO_2$ ∴ 28g/100mL, or 28,000mg/100mL, or 280,000mg/L.

[601] Molar mass of $NaClO_2$ = 90.5g/mol and molar mass of $^-ClO_2$ = 67.5g/mol ∴ 280,000mg/L × 67.5/90.5 = 208,840mg/L $^-ClO_2$.

[602] Mark Grenon "MMS Instructions" (2017) <https://miraclemineral.co.nz/index.cfm?fact=instructions>.

[603] One drop of water is 0.05mL, and if the WPS1 is presumed to be diluted in a glass of water, that is 300mL. Consequently, 0.05mL × 6 drops = 0.3mL.
280,000mg/L × 0.3mL/1000 = 84mg.

84mg/300mL = 0.28mg/mL ≡ 280mg/L $NaClO_2$.

[604] 280mg/L $NaClO_2$ × 67.5/90.5 = 208mg/L $^-ClO_2$.

[605] Methemoglobinemia is a condition characterised by abnormally high amounts of methemoglobin in the blood which causes problems with the oxygen-binding of haemoglobin.

[606] Medsafe, above n 593; G Amy and others *Disinfectants and Disinfectant By-Products* (World Health Organisation, online ed, Geneva, 30 November 2004), at 103-104.

faster than the subject's body can handle, advising continued usage at a lower dose.[607] However, this type of information has already resulted in death from MMS, and could feasibly lead to many more.[608]

6.2.3 The sale and marketing of MMS in NZ

Following the trend of the USA, Canada, and the UK, Medsafe issued a statement late in 2010 warning the public of the risks posed by MMS.[609] This followed a 2009 warning from Medsafe to the NZ distributor that the online advertising was in breach of the MA due to high-level TCs, without MMS having approval for sale as a medicine.[610] Despite this, MMS has continued to be available in NZ, although under a unique arrangement which uses different websites to separate advice and instructions on the use of the products from their sale. The NZ website 'Miracle Mineral' provides extensive information on MMS,[611] including numerous disclaimers noting; "MMS products are not medicines or drugs"[612] or variants on that theme. Presumably, the TCs which caused the 2009 Medsafe letter have been removed from the website;[613] however, there remain several factors which indicate attempts to circumvent this prohibition. While the website does not contain direct TCs and includes disclaimers, it appears designed to send a different message by directing consumers to external websites which make the claims, or by attempting to discredit research and government publications which cast doubt on MMS products.[614]

Three specific elements suggest the seller's attempts at coming as close as possible to making a TC, without overstepping the line. First, in a supposed letter to customers on the homepage, the website notes that;[615]

> … regardless of the many thousands of success stories worldwide, and recommendations that you may have heard from family and friends; this website cannot and will not make any public claims that MMS 'treats' or 'cures' serious diseases or conditions …

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[607] Grenon, above n 602.
[608] Mark Russell "'Miracle' elixir linked to death, illness" *The Sydney Morning Herald* (online ed, Sydney, 22 August 2010); BJ Skane "Health authorities 'Down Under' concerned over "snake oil" MMS promotional tours" *Vanuatu Daily Post* (online ed, Vanuatu, 11 November 2014).
[609] Medsafe, above n 593.
[610] Letter from Carole Firth, (Advisor, Medsafe) to Anon. (www.miraclemineral.co.nz) Compliance with the Medicines Act 1981 (13 February 2009).
[611] Mark Grenon "Miracle Mineral" (2017) <https://miraclemineral.co.nz/index.cfm?fact=purchaseproduct>.
[612] At 1.
[613] Firth, above n 610.
[614] Grenon, above n 611; further to this point, the website makes use of logical fallacies, which attempt to conflate the food sterilisation and water purification uses of chlorine dioxide with the purported medicinal uses of MMS by way of the statement on the homepage: "MMS is used to make chlorine dioxide, a proven pathogen killing mineral used extensively in the hygiene and water treatment industries… The human body is 60-70% water."
[615] At 1.

wherein the letter explicitly lists 35 conditions which MMS elsewhere claims to treat. The use of 'cannot … make any public claims' followed by a long list of claims is perhaps designed to send the opposite message – that the product can do what it claims, but Government regulations do not permit the company to make such statements. The second factor is frequent reference to Humble's book, which the website sells.[616] Therein, frequent TCs are made, with instructions on how to formulate MMS for treatment of specific medical conditions, including the 35 mentioned above.[617] Finally, the website contains a page dedicated to 'success stories'.[618] This page contains over 150 'testimonies', organised by condition, from people who have used MMS. The website displays multiple high-level TCs relating to many imaginable conditions, and yet avoids making these claims directly. The overall impression of this website is that it indicates a large number of therapeutic purposes for MMS, yet ostensibly does not make claims to this effect itself, instead pointing consumers to other sources which make the claims; all of which are published directly or indirectly on their website.

The final aspect to NZ MMS marketplace is the separation between the site providing information, and the seller. Every page on the MMS website displays a disclaimer avoiding any responsibility for products or links to material on 'third-party' sites. When attempting to purchase MMS products from this website, the prospective customer is sent to a page, which carefully explains how to concoct the various preparations from the concentrate, and is then sent to a site which purports to specialise in water purification – NZ Water Purifier Ltd.[619] Under the auspices of a shop specialising in water purification for agricultural, travel, or home water treatment needs, NZ Water Purifier sells a niche range of products in inexplicably small volumes, alongside similarly small spray and dropper bottles, and gelatine capsules.[620] Furthermore, the Miracle Mineral website notes that none of the products distributed from the NZ Water Purifier site come with instructions of any kind.

Through these convoluted mechanisms, MMS and its NZ sellers have avoided any further altercations with Medsafe. This raises questions on whether MMS now fits in the NZ regulatory matrix, and whether its attempts to circumvent restrictions on TCs are sufficient to evade regulation as a medicine.

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[616] At 1.
[617] Humble, above n 582.
[618] Mark Grenon "Miracle Mineral: Success Stories" (2017) <https://miraclemineral.co.nz/index.cfm?fact=Stories>.
[619] NZ Water Purifier Ltd, above n 600.
[620] At 1.

6.3 Food, Medicine or CAM Product?

Having established the background to MMS and an outline of its marketing and sale in NZ, it is possible to consider how it may be classified in light of the regulatory regimes considered in Chapters 2-5.

6.3.1 MMS as a food

There are some factors that indicate MMS could be a food.

MMS is a water-based product, with the addition of sodium chlorite. This could fall within the definition of food at s9 FA in that sodium chlorite is added to a drink.[621] In addition, water-based products are specifically included as being subject to food control plans in Schedule 1 FA. Similarly, a chlorite solution is used to sanitise chicken, to prevent campylobacter contamination, which also brings it well within the scope of the FA. A further argument that MMS is 'food' can be found in the fact that derivatives of sodium chlorite are included in the Health (Drinking-Water) Amendment Act[622] which modifies the Health Act 1956; and acceptable levels of chlorite in water are also set out in the NZ Drinking Water Standards.[623] This suggests that MMS falls within the purview of drinking water, and therefore arguably food.

On the other hand, it could be argued that the concentration of the product sold through NZ Water Purifier is more akin to bleach than drinking water, and that there is a complete lack of any of the marketing material or sale information indicating that this product could be a 'food' or similar product.[624] Consequently, it appears that the argument that MMS is a food would be difficult to establish.

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[621] Food Act 2014, s9(1)(b)(iv)-(v); "9 Meaning of food
(1) In this Act, unless the context otherwise requires, food—
(b) includes—
(iv) any ingredient or other constituent of any food or drink, whether that ingredient or other constituent is consumed or represented for consumption on its own by humans, or is used in the preparation of, or mixed with or added to, any food or drink; and
(v) anything that is or is intended to be mixed with or added to any food or drink;"

[622] Health (Drinking-Water) Amendment Act 2007.

[623] Drinking-water Standards for New Zealand 2005 (Revised 2008), at 8.

[624] This would tend to indicate that the intention is not for the product to be consumed internally by humans, especially when the NZ Water Purifier website is considered in isolation from the MMS website. Intention is important in s9(1)(b)(iv)-(v), see footnote 621.

6.3.2 MMS as a medicine

There is a stronger argument that MMS is a medicine, or at least a related product under the MA.[625] This was the approach taken by Medsafe in 2009 when the letter was sent to MMS requiring them to bring their website in line with the MA.[626] Before delving into the possibility of MMS as a medicine, it is beneficial to consider the similar case of *New Health New Zealand Inc. v Attorney-General*,[627] which considered whether fluoride added to the water supply was a medicine.

New Health is an interest group, which has taken multiple cases in the past decade against local and national government on the fluoridation of water. In the case at hand, the plaintiff's argument sought declarations that fluoride was a medicine, and consequently subject to the MA and Medicines Regulations, in reliance on an earlier case they took against South Taranaki District Council.[628] While Collins J acknowledged that fluoride was added to the water supply for a therapeutic purpose, and administered to the public through the water,[629] he ultimately held that the phrase "unless the context otherwise requires" in s3 MA when determining what amounts to a medicine allowed a contextual approach to be taken,[630] resulting in fluoride at such low concentrations as present in water to be outside the scope of a medicine in the MA.[631] This decision was made even though fluoride is present in Schedule 1 MRs as a prescription, restricted and pharmacy-only medicine, as well as listed online as a general sale medicine.[632] Despite handling a similar conceptual issue between *New Health* and MMS, of a chemical being added to water, the relevance of *New Health* to MMS is best limited to a general indication of the flexibility afforded to the courts to determine what constitutes a medicine or related product, notwithstanding apparently strict definitions of both in the MA.

Returning to MMS, it has been discussed above how the website comes exceedingly close to claiming therapeutic benefits from consumption of MMS. This is seen through a combination of negatively worded TCs where more than 35 conditions are listed, the links to external websites, and the publication of 'testimonies' for named, and often high-level conditions. The difficulty with establishing MMS as a medicine under the definition in s3 of the MA is that scientific evidence suggests it will not have a pharmacological, immunological or metabolic mechanism for achieving its claimed therapeutic

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[625] Medicines Act 1981, s94(1); "In this Part, unless the context otherwise requires, the term related product means any cosmetic or dentifrice or food in respect of which a claim is made that the substance or article is effective for a therapeutic purpose;"
[626] Firth, above n 610.
[627] *New Health New Zealand Inc v Attorney-General* [2014] NZHC 2487.
[628] *New Health New Zealand Inc v South Taranaki District Council* [2014] NZHC 395, [2014] 2 NZLR 834.
[629] *New Health New Zealand Inc v Attorney-General*, above n 627, at [34]-[39].
[630] See footnote 633, below.
[631] *New Health New Zealand Inc v Attorney-General*, above n 627, at [40]-[51].
[632] At [28], and [30]-[31].

purpose.[633] Unless a court adopted a relaxed approach to the definition of medicine under s3, any action under the MA would have to proceed under s94, claiming that MMS is a 'related product'.

To be a related product under s94(1) MA, two criteria must be satisfied. The product must be a cosmetic, dentifrice, or food, and there must be a claim that the product is effective for a therapeutic purpose.[634] For the purposes of this section, MMS could be considered a food, as discussed at 6.3.1, and as seen in the discussion in the preceding paragraph, it is likely that the MMS website contains sufficient material to amount to a TC, thus meeting both criteria. While MMS does not naturally come within the definition of food, it is likely that a court would be willing to stretch the definition of food or related product, if it held that MMS could not be classified as a medicine. If MMS were held to be either a medicine, or a related product (namely a food making TCs),[635] it would amount to a breach of s20 MA which prohibits sale, supply or advertisement of availability of a new medicine or related product.[636]

On the other hand, it would be possible to counter such a case on the grounds that these products are chemicals, as sold through NZ Water Purifier, primarily intended for water purification, and not intended for human consumption.[637] Further, due to the dearth of any evidence of efficacy in support of its health claims, it is unlikely that MMS could feasibly be registered as a medicine, so if the option of MMS as a related product was unavailable, the MA would not be applicable. However, the apparent close association between the MMS website, and that of NZ Water Purifier is very likely to bring such a case within the ambit of ss94 and 20 MA with MMS being a related product or a new medicine.[638]

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[633] Medicines Act 1981, s3(1)(a); "3 Meaning of medicine, new medicine, prescription medicine, and restricted medicine

(1) In this Act, unless the context otherwise requires, medicine—

(a) means any substance or article that—

(i) is manufactured, imported, sold, or supplied wholly or principally for administering to 1 or more human beings for a therapeutic purpose; and

(ii) achieves, or is likely to achieve, its principal intended action in or on the human body by pharmacological, immunological, or metabolic means;"

[634] At s94(1); see footnote 625. There are also three categories of which the product may not be a part, including 'any medicine', but this is not relevant for the present discussion.

[635] At s94(1); and At s96(1); "96 Certain provisions to apply to related products as if medicines

(1) Sections 20 to 22, and 35, with all necessary modifications, shall apply to new related products in the same manner and to the same extent as they apply to new medicines."

[636] Section 96 MA notes the application of s20 (amongst other sections) to related products in the same way they apply to new medicines. This effectively means s20 can be read "Restrictions on the sale or supply of related products" instead of "Restrictions on the sale or supply of new medicines".

[637] This would imply that it is not a food, and therefore cannot amount to a related product.

[638] As previously noted, the MMS NZ website (www.miraclemineral.co.nz) directs consumers to the NZ Water Purifier website on multiple occasions for the purpose of purchasing MMS products, clearly describing which of the NZ Water Purifier products correspond identically to the MMS 'sacraments'. Additionally, NZ Water Purifier

6.3.3 MMS as a CAM product

Finally, it is possible that there could be an argument that MMS is a CAM product, or more pertinently, a DS within the purview of the DSRs, or a 'natural health and supplementary product' within the NHSPB.

As a remedy which has little scientific evidence behind it in respect of its efficacy or safety, and yet allegedly attracts vast numbers of proponents, MMS certainly falls within the wide ambit of CAM products. However, insofar as the DSRs are concerned, establishing a breach is slightly more difficult. Contrary to the claims of proponents online,[639] MMS is not a mineral per s2A DSRs, and due to its toxicity and lack of evidential basis, is also unlikely to be considered a synthetic nutrient within the meaning of s2A. Furthermore, since legal action in the USA, MMS is no longer called 'Miracle Mineral Supplement', but rather goes by the name 'Miracle Mineral Solution', likely annulling any argument that MMS comes within the remit of the DSRs for stating 'supplement' in its name.

While it could be considered a CAM product in a general sense, it is unlikely that MMS is a DS. Similarly, it would be difficult to argue that it is a 'natural health and supplementary product' within the definition provided in cl6 NHSPB. That clause required that the product bring about a health benefit, which MMS will almost certainly not do, as well as requiring the product to only contain permitted ingredients. Currently, chlorite or sodium chlorite are not permitted ingredients,[640] and therefore it is very unlikely that MMS could have been a natural health and supplementary product under the NHSPB.

6.4 Conclusion

MMS is a fairly extreme example of a CAM product which defies classification. It does not come under the DSRs, nor does it readily fit within the FA due to difficulties reconciling a liquid more akin to bleach than water with the Act, and the absence of an objective intent for chlorite to be consumed as a food. There is certainly an argument that MMS is a related product or a new medicine under the MA, and while there would be a reasonable chance of success with such an argument, it remains an unnatural

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sells nothing else which could be considered to come within the normal business of a water purification company (e.g. pumps, filters, pool cleaning or purifying supplies), except for the MMS products and associated paraphernalia. Finally, the physical address for the NZ Water Purifier website is the same as that of the MMS conference held in 2014, attended by the leading members of the Church of Health and Healing. Smith, above n 581.

[639] Grenon, above n 611.

[640] As at the time of writing, hypochlorus acid (HClO) and sodium hypochlorite (NaClO) were proposed to be permitted ingredients on the list, but these both have distinct chemical composition to chlorite or sodium chlorite; Ministry of Health, above n 550.

fit. In order to classify MMS as a related product, it must be established that it is a food, requiring the definitions of either food or related product to be stretched to bring MMS within this ambit. While the recommended dose of MMS is significantly diluted, any toxicity is unacceptable in line with a risk management framework like the FA, given the non-existent benefit of MMS beyond the placebo effect.

In short, there is no obvious or logical classification for MMS. This poses problems in a practical sense, as enforcement against products such as this can be extremely difficult when they make unsubstantiated TCs, or actively mislead and deceive consumers as to their purpose or efficacy. Consequently, consumer protection legislation steps in where primary legislation is unable to police these types of products, and as seen in Chapter 7, it provides some scope to address unsafe, false, or misleading conduct by products such as MMS.

Part II: General Legislation & A Broader Perspective

7 The Fair Trading Act 1986 & the Consumer Guarantees Act 1993

7.1 Introduction

Part I considered specific legislation surrounding CAM products, with a review of food legislation, as well as medicines legislation. That Part finished with a brief look at the case study of MMS and the application of the FA, MA, DSRs, and NHSPB to that case. It concluded that while the FA, DSRs, and NHSPB are unlikely to be applicable, it may be arguable that MMS is covered under the MA, although this is far from certain. If these specific Acts are not able to regulate CAM products, an alternative option is to consider the applicability of general legislation. Even if specific legislation is available, general legislation may currently be seen as preferable, if it contains remedies that are more appropriate than those available through the primary legislation.

This Chapter will consider the use of the FTA and CGA as alternative means of regulation. It will also revisit the case study of MMS and consider whether the FTA or CGA would provide a more appropriate remedy.

7.2 The Fair Trading Act 1986

The FTA was designed to be a general piece of consumer protection legislation that could not only respond to a constantly changing commercial environment, but also act as a complementary piece of legislation to the Commerce Act 1986, which aimed to ensure a well-regulated competitive marketplace in NZ.[641] This purpose is embodied in s1A FTA,[642] which notes at subs(2) that the Act aims to achieve this by, amongst other things, prohibiting unfair conduct and practices in trade,[643] and promoting safety in relation to goods.[644] Of the six parts to the Act, Part I, which deals with unfair conduct, and Part V, concerning enforcement and remedies, are relevant to the following discussion.

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[641] Lindsay Trotman and Debbie Wilson *Fair Trading: Misleading or Deceptive Conduct* (1st ed, LexisNexis, Wellington, 2006), at 1-2.
[642] As inserted by the Fair Trading Amendment Act 2013, s5. Prior to this, the long title stated: "An Act to prohibit certain conduct and practices in trade, to provide for the disclosure of consumer information relating to the supply of goods and services and to promote product safety and also to repeal the Consumer Information Act 1969 and certain other enactments".
[643] Fair Trading Act 1986, s1A(2)(a).
[644] At s1A(2)(d).

7.3 Section 9 FTA

7.3.1 Overview

In contrast to the other sections of Part I FTA, s9 is unique in its breadth, as demonstrated by the title 'misleading and deceptive conduct generally'.[645] This section states "No person shall, in trade, engage in conduct that is misleading or deceptive or is likely to mislead or deceive."[646] In line with the broad scope of this section and its consumer focus, an objective standard is applied, requiring consideration of whether a reasonable person was likely to be misled by the conduct. Furthermore, there is no requirement for the defendant to have intended to mislead.[647]

A breach of s9 results in the availability of civil remedies in the form of injunctions,[648] orders for disclosure or corrective advertising,[649] and remedial orders between affected parties,[650] including refunds or damages for loss.

7.3.2 Tests

A reading of s9 suggests that three criteria must be met: that the person is in trade, that the person engages in conduct, and that the conduct is misleading or deceptive.[651] The discussion in this Chapter will focus on the third element; whether conduct that is misleading or deceptive can be established in relation to CAM products. It will be assumed that someone advertising or selling CAM products will satisfy the first and second criteria in the majority of cases.[652]

The initial test for breach of s9 was a three-stage formulation by the Court of Appeal in *AMP Finance NZ Ltd v Heaven*.[653] It stipulated that the question of whether there was a breach of s9 should first consider whether the conduct was capable of being misleading, secondly whether the plaintiff was actually misled, or that other people were likely to be misled,[654] and thirdly, the objective test of whether a reasonable person would have been misled by the same conduct.[655]

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[645] At s9.
[646] At s9.
[647] Trotman and Wilson, above n 641, at 3-4.
[648] Fair Trading Act 1986, s41.
[649] At s42.
[650] At s43.
[651] *Red Eagle Corporation Ltd v Ellis* [2010] NZSC 20, [2010] 2 NZLR 492, at [26]-[28].
[652] *Glorie v WA Chip & Pulp Co Pty Ltd* (1981) 55 FLR 310, 39 ALR 67 (FCA); *Pharmaceutical Management Agency Ltd v Researched Medicines Industry Association New Zealand Inc.* [1996] 1 NZLR 472 (HC).
[653] *AMP Finance NZ Ltd v Heaven* (1997) 8 TCLR 144 (CA).
[654] Trotman and Wilson, above n 641, at 4.
[655] *AMP Finance NZ Ltd v Heaven*, above n 653, at 152.

In 2010, the Supreme Court revisited the test, in *Red Eagle Corporation v Ellis*,[656] and took an alternative approach. This did not overrule *AMP v Heaven*, but rather provided an analysis which might be more appropriate in the particular circumstances of a case.[657] Blanchard J delivered the Court's decision, outlining the new test:[658]

> The question to be answered in relation to s9 in a case of this kind is accordingly whether a reasonable person in the claimant's situation – that is, with the characteristics known to the defendant or of which the defendant ought to have been aware – would likely have been misled or deceived.

The test then turns to whether a remedy can be awarded under s43; questioning first whether the plaintiff was actually misled or deceived by the defendant's conduct, and if so, whether said conduct was an operating[659] cause of the plaintiff's loss.[660]

It should be noted that while the test in *Red Eagle* is commendable for its simplicity and more accurately reflects the language of s9, its application usually involves a party who has directly suffered loss, rather than a consumer protection body like the CC. This is demonstrated by almost all the cases which apply this precedent.[661] If there is no direct loss, for example in situations where the CC is taking action against misleading or deceptive conduct to protect consumers, then *AMP v Heaven* might be the most appropriate formulation.

Under both tests, there is one particular element which has been utilised in establishing whether conduct actually misleads or deceives the public that is worth considering. That is the use of surveys, primarily, to provide evidence of broad public confusion.[662] In general, survey evidence under the FTA has been deemed admissible in NZ, although as one of the leading cases noted, the sample should be representative of a cross-section of NZ society.[663] Where this has not been the case, or in the event of substantial problems with the survey design, the courts have held that survey evidence may still be

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[656] *Red Eagle Corporation Ltd v Ellis*, above n 651.
[657] Thomas Gault (ed) *Gault on Commercial Law* (online looseleaf ed, Thomson Reuters), at [FT9.06(4)].
[658] *Red Eagle Corporation Ltd v Ellis*, above n 651, at [28].
[659] At [29]; Blanchard J goes on to clarify the term 'operating cause', noting; "Put another way, was the defendant's breach *the* effective cause or *an* effective cause?"
[660] *Red Eagle Corporation Ltd v Ellis*, above n 651, at [29].
[661] *E-Trans International Finance Ltd v Kiwibank Ltd* [2016] NZHC 1031, [2016] 3 NZLR 241; *Aldrie Holdings Ltd v Clover Bay Park Ltd* [2016] NZHC 250, (2016) 17 NZCPR 127; *Interclean Industrial Ltd v Camp* [2015] NZHC 3177; *Batchelar Centre Ltd v Westpac New Zealand Ltd* [2015] NZHC 272, (2015) 15 NZCPR 726 etc.
[662] Trotman and Wilson, above n 641, at 148-151.
[663] *Levi Strauss & Co v Kimbyr Investments Ltd* [1994] 1 NZLR 332 (HC); Gault, above n 657, at [FT9.22(2)].

admissible, but will have lower probative value.[664] The importance of surveys in establishing evidence of misleading or deceptive conduct will be returned to in Part III.

7.3.3 Cases

There are almost no NZ cases which use s9 FTA to handle misleading or deceptive conduct in respect of a CAM product. There are a number of possible reasons for this; including the fact that only civil remedies are available under s9, the CC's apparent preference for settlement or negotiation over litigation,[665] and s10 having a lower burden of proof than s9.[666] One relevant NZ case is *CC v New Zealand Nutritionals*,[667] which concerned the sale of goats' milk tablets and powder that was incorrectly labelled as '100% NZ made'. Action was taken by the CC under s9, s10 and s13(j) FTA, and the Court found in their favour on all three counts, on the basis that the labelling led the type of consumer who would buy goat's milk DSs to believe that the product was made in NZ, and this would likely be material in their purchasing decision.[668] The value of declarations by the HC of the breaches under ss9, 10 and 13(j), was deemed appropriate for deterring similar conduct from other companies.[669]

Two Australian cases provide a more relevant consideration of the application of the Australian equivalent to s9 FTA; the former s52 Trade Practices Act 1974 (Cth),[670] and the near identically worded Victorian state statute, s9 Fair Trading Act 1999 (Vic).[671] Decided a mere month apart, these two cases demonstrate contrasting approaches to the application of the prohibition on misleading or deceptive

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[664] *Cookie Time Ltd v Griffins Foods Ltd* HC Auckland, M1756/SW00, 11 December 2000; *Anheuser-Busch Inc v Budweiser Budvar National Corp* [2003] 1 NZLR 472 (CA).

[665] See Baa Baa Beads case, discussed at 7.7.3. This is an example of the CC using its s12A powers to avoid litigation due to the expense and potential for failure. With the introduction of enforceable undertakings in Part V FTA by way of the Fair Trading Amendment Act 2013, it is likely that more cases will be settled out of court.

[666] See discussion at 7.4.2 on the difference between s9's 'likely to mislead or deceive', and s10's 'liable to mislead'.

[667] *Commerce Commission v New Zealand Nutritionals (2004) Ltd* [2016] NZHC 832.

[668] At [36]-[39].

[669] At [66].

[670] Trade Practices Act 1974 (Cth); "52 Misleading or deceptive conduct

(1) A corporation shall not, in trade or commerce, engage in conduct that is misleading or deceptive or is likely to mislead or deceive.

(2) Nothing in the succeeding provisions of this Division shall be taken as limiting by implication the generality of subsection (1)."

[671] Fair Trading Act 1999 (VIC); "9 Misleading or deceptive conduct

(1) A person must not, in trade or commerce, engage in conduct that is misleading or deceptive or is likely to mislead or deceive.

(2) Nothing in the succeeding provisions of this Part is to be taken as limiting by implication the generality of sub-section (1)."

conduct; one where opinions were held to trump scientific evidence, and the other where expert testimony ultimately demonstrate the misleading nature of the claims.

In *Director of Consumer Affairs v Operation Smile*,[672] a range of claims were made on the defendant's website; from definite statements of fact, like claims around treatment of cancer,[673] to more oblique claims concerning extension and improvement of life.[674] The Supreme Court of Victoria held that freedom of expression must be balanced against the requirements of s9 Fair Trading Act 1999 (Vic),[675] and these claims were a matter of opinion. Despite the fact they directly contradicted established scientific evidence and conventional medicine, they were nevertheless outside the scope of misleading or deceptive conduct. The Court reasoned that the combination of a disclaimer, and arguable presentation of the statements as opinions excluded them from action under the Fair Trading Act 1999 (Vic).[676]

The second case is *ACCC v Willesee Healthcare*.[677] In this case, the defendant was selling and advertising CAM products, therapies and resources which claimed to treat, test or cure allergies; especially in children.[678] While the Court in *Operation Smile* did not see its role as interpreting questions of fact, the Federal Court in *Willesee* held, on the basis of evidence from expert witnesses, that the products could not possibly achieve those representations, and therefore they were misleading and deceptive[679] under the Trade Practices Act 1974 (Cth).[680]

7.3.4 Remedies

As previously noted, the remedies available under s9 are civil remedies.[681] In *CC v New Zealand Nutritionals*, a declaration was issued by the Court. In *Operation Smile*, the case was dismissed,[682] but

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[672] *Director of Consumer Affairs (Vic) v Operation Smile (Australia) Inc (No 2)* [2011] VSC 153.
[673] At [59]; "SUCCESSFULLY TREATED DISEASES … Cancers including Gastrointestinal, Thyroid, Pancreas, Breast Cancer with brain metastases, Cervical cancers, Lymphoma, Leukaemia and many others …"
[674] At [65]; "In the majority of cases these treatments lead to an extension of life and an improvement in the quality of life."
[675] At [3]-[4].
[676] At [76]-[77]. The NZ position with respect to opinions is generally a 'wider view', whereby the most important aspect is that there is a genuine basis for the opinion that is reasonably based on available information, if it is not to be misleading or deceptive; *Phillips v King Pie New Zealand Ltd* HC Auckland CP165/98, 17 September 1999; *Mok v Bolderson* (2011) 13 TCLR 209 (HC). Even in spite of NZ's 'wider view' it is possible that a different decision would be reached in this particular case if it were to come before a NZ court, on the basis of other cases on opinion in NZ; at ; *Hamid v England* (2011) 13 TCLR 376 (HC).
[677] *Australian Competition and Consumer Commission v Willesee Healthcare Pty Ltd (No 2)* [2011] FCA 752.
[678] At (declaration) 1-2; The representations were that the products could; "cure or eliminate all or virtually all allergies, or allergic reactions…" and "successfully treat a person's allergies or allergic reactions…"
[679] At (declaration) 1-2 and [17]-[21].
[680] Trade Practices Act 1974 (Cth), ss52, 53(a), 53(aa), 53(c), 55 and 55A.
[681] See 7.3.1.
[682] *Director of Consumer Affairs (Vic) v Operation Smile (Australia) Inc (No 2)*, above n 672, at [101].

in *Willesee* the Court accepted civil measures in the form of enforceable undertakings made between the parties,[683] which required, inter alia, corrective advertising.[684]

There are a variety of remedies available under Part 5 FTA. Section 41 allows the courts to grant injunctions for breaches of Parts 1-4 of the Act. Insofar as s41 applies to s9, the most important part is the ability for the CC to apply for interim injunctions before taking the case to a full trial. Section 42 has a more practical application, allowing for the court to make an order, on application by the CC, either for disclosure of information, or publication of corrective advertising. This is a versatile remedy which could be used either in isolation for minor breaches, or in combination with other penalties where strong deterrence and public awareness of the misleading or deceptive conduct are sought.

Section 43 has more limited application, with it only applying where a person has suffered loss or damage, or where they are likely to suffer loss or damage. In the event of a contract between parties, there are various remedies under s43(3) around voiding or varying the contract. Subsection (3) also allows the court to make orders for refund,[685] repair,[686] or compensation for loss or damage by the offending party to the misled or deceived person.[687] For these remedies to be available, loss, damage, or expenditure will have to be shown by the misled or deceived individual, as these are not punitive penalties.

Finally, under ss46A and 46B FTA (and as seen in *Willesee*), the CC may make accept undertakings from a party in breach of the Act which are enforceable by the courts in the event of a breach. This allows the CC some flexibility and promotes cooperation where misleading or deceptive conduct may have been unintentional.

7.3.5 Application to MMS[688]

In order for an action against MMS to succeed under s9, the case must meet the test in either *Heaven* or *Red Eagle*. *Heaven* is probably the more appropriate test in this instance, as the case of MMS is not the 'straightforward' type of scenario for which the Supreme Court in *Red Eagle* designed its alternative test. Consequently, this application will consider whether MMS meets the requirements

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[683] *Australian Competition and Consumer Commission v Willesee Healthcare Pty Ltd (No 2)*, above n 677, at Annexure 1-6, and [73]; some defendants were required to pay pecuniary penalties as part of the enforceable undertakings, but given the limitation of s9 FTA to civil remedies, it is unlikely that this would be possible in NZ.
[684] At Annexure 1-6, and [73].
[685] Fair Trading Act 1986, s43(3)(e).
[686] At s43(3)(g).
[687] At s43(3)(f).
[688] See the facts around MMS at 6.2.

of being in trade, engaging in conduct, and involving conduct that is misleading or deceptive in accordance with the test in *Heaven*.

The fact that the MMS website is engaged in the promotion and advertising of the MMS products sold through NZ Water Purifier is sufficient to fall within the wide ambit of 'in trade' for the purposes of the FTA. Similarly, the promotion and advertising also amounts to conduct, meeting the second step for establishing liability under s9 in the case of MMS. Furthermore, as conduct includes omitting to do an act, any information which is left out of an advertisement would also meet the conduct criteria for s9.

The totality of the material on the MMS website is likely to be capable of being misleading or deceptive in line with the first step of the test in *Heaven*. Given elements on the website like the testimonies for specific diseases, and the appearance of scientific backing, it is plausible that the second step of the test may be met in that people are likely to be misled or deceived. This becomes more certain when the third stage is considered; whether it is reasonable for the plaintiff to have been misled. This is an objective test, which requires identification of a relevant section of the public,[689] and then a consideration of whether members of this group would be likely to be misled by the conduct. In this instance, the relevant section of the public is plausibly those who will have a preconception as to the efficacy of CAM. As it is likely that they would be misled by the conduct, the requirement under s9 for misleading or deceptive conduct would appear to be met in the case of MMS.

It is in an instance such as this where survey evidence may be extremely valuable to establishing the first and second stages of the test in *Heaven*. Were a survey to be conducted of a broad cross-section of NZers on their perceptions of the outcomes and efficacy of MMS based upon the information available on the website, it may provide evidence of misleading conduct. If a significant proportion of participants demonstrated that they were misled or deceived by the MMS website, then this would certainly provide evidence for the first step of *Heaven*, as well as having strong probative value, if not being determinative, for the second step, that people are likely to be misled or deceived, and the third step, whether it was reasonable for the people to have been misled.

In summary, it is highly probable that misleading and deceptive conduct can be established for MMS under s9 FTA on the grounds that consumers are likely to be misled. As a result, the civil remedies of injunctions, declarations, corrective advertising and enforceable undertakings would likely be available, on an application by the CC, on the basis that MMS is likely to mislead consumers under s9.

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[689] *Taco Co of Australia Inc v Taco Bell Pty Ltd* (1982) 42 ALR 177 (FCA), at 69-71, and 79.

If in specific cases, actual loss can be demonstrated, then the remedies under s43 would also be available.

7.4 Section 10 FTA

7.4.1 Overview

Section 10 FTA is largely similar in terms of scope to s9, except that it narrows its breadth through application to goods alone, and only requires that the conduct be 'liable' to mislead; a lesser standard than 'likely to' mislead. The section states "No person shall, in trade, engage in conduct that is liable to mislead the public as to the nature, manufacturing process, characteristics, suitability for a purpose, or quantity of goods."[690]

Breach of s10 may result in criminal liability under s40 FTA if relevant charges can be established beyond reasonable doubt. The penalties under s40 involve a maximum fine of $200,000 for an individual and $600,000 for a body corporate.[691] A breach may also result in civil liability, as discussed in relation to s9.

7.4.2 Tests

The concept of 'misleading conduct' applies to s10 in a similar way as 'misleading and deceptive conduct' applies in s9,[692] as the omission of 'deceptive' has no effect on the interpretation. What is pertinent to s10 is the distinction between 'liable to mislead' compared to s9's 'likely to mislead'.

Sound Plus v CC[693] established that 'liable to mislead' imputes a lower burden than 'likely to mislead'. The standard for 'liable to mislead' was held to be one of "…a potential less than likelihood or probability…"[694] This has built upon similar cases,[695] which argued that the standard is nearer to 'possible', or as *Sound Plus* states "subject to the possibility of".[696] Consequently, while s10 limits its application, especially in comparison with s9, to goods and misleading conduct relating to their nature and characteristics, it is nevertheless a slightly easier threshold of proof to establish that the conduct has been misleading when it falls within the ambit of s10 in relation to goods.

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[690] Fair Trading Act 1986, s10.
[691] At s40(1).
[692] See 7.3.2 for analysis of misleading or deceptive conduct.
[693] *Sound Plus Ltd v Commerce Commission* [1991] 3 NZLR 329 (HC).
[694] At 332.
[695] *Air New Zealand Ltd v Commerce Commission* [1985] 2 NZLR 338 (HC).
[696] *Sound Plus Ltd v Commerce Commission*, above n 693, at 332.

7.4.3 Cases

Zenith Corporation v CC[697] was an appeal from earlier proceedings in the DC.[698] The case concerned 49 offences, which largely centred on advertisements and claims associated with Zenith's product 'Body Enhancer'. These claims ranged from weight-loss advertisements to healing and improvement of cartilage and bones.[699] The CC brought the initial action under s10 on the basis that the advertising and promotional material was "liable to mislead the public as to the nature or suitability for the purpose of the product", with charges in the alternative under s13.[700] Liability was established under s13, and therefore s10 was not required to be considered.[701]

CC v Erdic also concerned charges brought under both ss10 and 13(a),[702] relating to multiple claims made on brochures and websites relating to 'Erdic' – a plant-based food supplement breast beautifying programme.[703] This product claimed to "…make female breasts firmer, fuller and more beautiful",[704] despite containing neither estrogenic compounds, nor any other hormone which would have this effect. As a result, Judge Kerr held that this conduct was proven to be false and misleading, as the product was not doing what it claimed,[705] and thus held that the s10 charges were proven beyond reasonable doubt.[706]

While not directly relevant to CAM products, one recent case does provide a valuable illustration of s10's utility in respect to medicines.[707] In the widely publicised case of *CC v Reckitt Benckiser*,[708] Reckitt Benckiser, the NZ distributor of the NSAID 'Nurofen', pleaded guilty to 10 charges under s10 relating to claims on their products that they provided targeted pain relief for specific types of pain. As it eventuated, all the products were identical, and contained no distinct ingredients. The only element

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[697] *Zenith Corporation Limited and Anor v Commerce Commission*, above n 308.
[698] *Commerce Commission v Zenith Corporation Ltd*, above n 307.
[699] *Zenith Corporation Limited and Anor v Commerce Commission*, above n 308, at [7].
[700] At [1].
[701] At [61]-[64].
[702] *Commerce Commission v Erdic (NZ) Limited* DC Tauranga CRI-2006-070-006303, 15 August 2008.
[703] At [8] and [3].
[704] At [4].
[705] At [12].
[706] At [46]. See discussion at 7.5.2 on how representations may, on some occasions, amount to conduct. This appears to have been the position taken in *Erdic*.
[707] Most cases involving CAM products have not addressed the question of efficacy as *CC v Reckitt* Benckiser did. The Commerce Commission has been quoted on occasion stating: "It is not the Commission's role to decide on the efficacy of alternative health practices…" Commerce Commission "Bird flu remedy is quackery" (press release, 15 January 2009). Consequently, s10 has arguably been underutilised in cases of this kind, see *Commerce Commission v John Graham Godwin and Anor*, above n 161, *Zenith Corporation Limited and Anor v Commerce Commission*, above n 308, and *Honey New Zealand (International) Limited v Director General of the Ministry for Primary Industries*, above n 160, for example, with the Commission instead being more likely to take action on the basis of representations under one of the subsections of s13.
[708] *Commerce Commission v Reckitt Benckiser (New Zealand) Ltd* [2017] NZDC 1956, [2017] DCR 431.

of difference was the labelling, which purported to claim efficacy for one of the four type of pain for which the products was marketed.[709] The Court considered this to be a straightforward application of s10, stating that the defendant's claims 'grossly misled' the public with respect to the characteristics and suitability for purpose of the goods.[710]

7.4.4 Remedies

In all three of these cases, criminal liability was established, and the defendants were fined under s40 FTA.

In addition to the criminal sanctions under s40, and the civil sanctions, as discussed at 7.3.4, there is one other remedy which may be applicable for offences under s10; management banning orders.[711] Where an individual has breached s40 FTA at least twice in a 10-year period, the court may ban the person from being a director, or managing a company in any way for up to 10-years.[712] Subject to certain conditions, this allows the court to protect the public from individual directors who have a history of breaching s40 FTA,[713] and through either course of action, strongly disincentivise such conduct by directors of a company.

7.4.5 Application to MMS

Applying s10 FTA to the example of MMS is largely similar to the application of s9, barring a couple of key differences. MMS and NZ Water Purifier are clearly in trade, and engaging in conduct; the main question is whether this conduct is liable to mislead the public in relation to the goods. *Erdic* clearly established that while a website may not have been created by the defendants, their use of the website for advertising and the proximity of the website was sufficient there for the purposes of s10, as it almost certainly would be in the case of MMS.[714] There is no question here that the conduct in the MMS example relates to goods, and given the argument at 7.3.5 that the conduct was 'likely to mislead or deceive' pursuant to s9, it will almost certainly reach the lower standard of 'liable to mislead'. Finally, three of the specific conducts stipulated in s10 could apply to MMS; misleading conduct as to either the nature, characteristics, or suitability for a purpose of the goods.[715]

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[709] At [5]; these forms of pain were 'Migraine Pain', 'Tension Headache', 'Period Pain', and 'Back Pain'.
[710] At [21].
[711] Fair Trading Act 1986, s46C.
[712] At s46D.
[713] At s46C Management banning orders.
[714] *Commerce Commission v Erdic (NZ) Limited*, above n 702, at [13]-[14].
[715] Fair Trading Act 1986, s10.

Once again, survey evidence would be valuable here, as it could not only establish the conduct as misleading, but aid in surmounting the burden of proof for criminal liability.

Thus, in theory, s10 would provide a suitable platform from which to bring charges against a product like MMS, either alone, or as an alternative to actions under ss9 or 13; additionally enabling sizeable fines as seen in *CC v Reckitt Benckiser*, which would certainly have a deterrent effect.[716] However, in practice the CC has shown an inclination to avoid s10 insofar as CAM products are concerned, and instead focus on s13 and the broad number of false or misleading representations which may encompass a particular case. This would be the first of three strikes towards a management banning order under s46C.

7.5 Section 13 FTA

7.5.1 Overview

Section 13 is somewhat distinct from the previous sections considered, primarily in that it deals with false or misleading 'representations' as opposed to 'conduct' as found in ss9 and 10. The distinction between s9 and s13 was highlighted by Tipping J in *Marcol Manufacturers Ltd v CC* when he stated, "…a representation…is of course a narrower concept than conduct generally".[717]

There are 10 types of false or misleading representations under s13, and while a variety of these subsections are employed throughout the cases concerning CAM products,[718] the most relevant is s13(a), which addresses false or misleading representations; "…that goods are of a particular kind, standard, quality, grade, quantity, composition, style, or model, or have had a particular history or particular use…"[719]

The penalties for a breach of s13 are identical to those for a breach of s10, as discussed at 7.4.1 and 7.4.5.

7.5.2 Tests

A breach of s13 requires that there be a representation, which is made in trade, in connection with the supply or possible supply of the goods or services or with the promotion of the supply or use of

[716] While there were a number of charges in *Reckitt Benckiser* which resulted in the $1.08m imposed fines, the Court noted that the size of the fines was indicative of the degree and knowledge which accompanies the conduct, as well as the need for deterrence.
[717] *Marcol Manufacturers Ltd v Commerce Commission* [1991] 2 NZLR 502 (HC), at 505.
[718] See 7.5.3.
[719] Fair Trading Act 1986, s13(a).

goods or services, and that the representation be false or misleading and accord with one of the 10 subsections.[720]

While the language of most of these elements is straightforward, 'representation' merits some discussion. The interpretation of 'representation' in NZ is well established, having been borrowed from the Australian case of *Given v Pryor*,[721] which looked at what entailed a representation under the equivalent section of the Australian Trade Practices Act.[722] In this case, Franki J established a broad ambit for representations, encompassing oral and written statements (even when associated with images), and in particular cases, may even include conduct.[723]

Tipping J adopted this position in *Marcol*, further explicating via a two stage test; the first question being one of law, whether the material can amount to a representation, and the second being one of fact, whether the material in question does amount to that representation.[724]

These interpretations have been followed since, although the two stage test in *Marcol* is seldom seen as necessary given the relative ease with which representations can be identified. Tipping J did take the opportunity in *Mega Vitamin Laboratories v CC* on appeal to note that there is not an unreasonable need for specificity or proximity of the representation to the product, with the pamphlet in question to that case clearly referring to the multi-vitamin tablets and thus the statements made on the pamphlet were capable of amounting to a representation.[725]

7.5.3 Cases

CC v Mega Vitamin Laboratories (NZ) Ltd[726] was an exceptionally important case which was arguably a perfect example of when the FTA should be used over primary legislation; namely for investigations which have the ultimate goal of otherwise unachievable consumer protection. In this case, the CC brought an action against Mega Vitamin under s13(a) FTA on the grounds that the label and brochures of the defendants' products 'falsely represented the composition of the goods',[727] which in practical terms meant that the quantity of vitamins listed on the labels was incorrect. The CC conducted analyses of the vitamin contents present in the defendants' multivitamins, and found the actual

[720] At s13; Gault, above n 657, [FT13] Synopsis.
[721] *Given v Pryor* (1979) 39 FLR 437, 24 ALR 422.
[722] Trade Practices Act 1974 (Cth).
[723] *Given v Pryor*, above n 721, at 446.
[724] *Marcol Manufacturers Ltd v Commerce Commission*, above n 717, at 506.
[725] *Mega Vitamin Laboratories (NZ) Ltd v Commerce Commission* (1995) 6 TCLR 231 (HC); Gault, above n 657, at [FT13.09(2)].
[726] *Commerce Commission v Mega Vitamin Laboratories (NZ) Ltd*, above n 305.
[727] At 97.

content to be between 54.4-87% of the stated amounts.[728] While Judge Green noted a willingness to adopt a *de minimis* principle in line with the Food Regulations 1984 such that a variability of 10% would be acceptable, the discrepancies were well outside this range, and ultimately the defendants' were found to be culpable.[729] This case is notable for the fact that the CC carried out an investigation and testing, which demonstrated misleading or deceptive representations not otherwise addressed in primary legislation. Furthermore, the Judge looked to the DSRs, but determined there was nothing in the Regulations which handled quantities of vitamins in DSs.[730] This case demonstrates an instance where the FTA is utilised not only as the best method for addressing misleading and deceptive conduct in relation to CAM products, but also as a valuable corollary to investigations of CAM products.

R v Muscle Marketing USA Ltd concerned a very similar situation, wherein the defendant's product, ATP Advantage Creatine Serum, made misleading statements as to its composition in breach of s13(a) FTA.[731] Judge Everitt took the opportunity to note the susceptibility of the people to whom this kind of product is marketed,[732] going on to state that this case falls squarely within the ambit of FTA legislation which aims to protect consumers from "…unwholesome claims, snake oil people and the like…"[733] No mention was made of the applicability of food legislation.

The charges under subs13(a) and (e) were successful in *Zenith*, (as discussed at 7.4.3) when argued in the alternative with charges under s10. The three charges under s13(a) were on the basis that the labelling on the 'Neo Nutrients Body Enhancer' made false representations as to the quality or composition of the goods.[734] The remaining 23 under s13(e) concerned "false representations as to the performance characteristics or benefit of the product."[735] The Court noted the four elements which had to be proved for liability under s13(e); namely that *Zenith* was a person, in trade, had made a representation in connection with the supply of the goods, and that representation was false or misleading.[736] Regarding evidence for this last requirement, the DC Judge accepted evidence from an expert witness, which established that the components of 'Body Enhancer' could not have the effect claimed, and thus the representations were misleading or deceptive.[737]

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[728] At 105.
[729] At 102 & 105.
[730] At 102.
[731] *R v Muscle Marketing USA Limited* DC Auckland CRN:2004048863, 14 July 2004, at [1].
[732] At [9].
[733] At [13].
[734] *Zenith Corporation Limited and Anor v Commerce Commission*, above n 308, at [1].
[735] At [1]; See above at 7.4.3 for a more detailed discussion on *Zenith*.
[736] *Zenith Corporation Limited and Anor v Commerce Commission*, above n 308, at [16].
[737] At [18]-[19].

CC v Godwin is something of an outlier to these cases in that it deals primarily with CAM practitioners rather than CAM products, but nevertheless demonstrates the applicability of s13.[738] The charges in this case were under subs(e) and (f), and amongst other things, represented their products as remedies for bird flu, herpes, SARS, and for use in an 'anti-terrorist kit'.[739] Despite these arguably being high-level claims, which at least indirectly indicated that they purport to cure otherwise incurable maladies, the Judge took a lenient approach; finding the defendants to be only careless, and not deliberately misleading, while also making obiter suggestions with respect to a scale for lessened penalties in cases such as these.[740] The relevance of intention in the decision in *Godwin* went to the sentencing, rather than a question of liability, with the defendants facing criminal liability under s40, albeit with reduced fines on the basis of their carelessness.

In 2010, the CC investigated a number of companies producing Royal Jelly products. Throughout these cases, there are two general themes upon which the various companies were prosecuted. The most prolific was the country of origin labelling issue, with all four cases facing charges under subs13(a) or (j) FTA.[741] More importantly, two cases faced charges regarding the alleged potency of their royal jelly products being much lower than claimed on the label. *CC v NZ Korea Health Ltd*[742] pled guilty to nine charges of misleading claims with respect to both the 10HDA[743] content of their products, which analysis showed to be approximately 7.83% of what was on the packaging, as well as to the country of origin labelling.[744] *CC v Honey New Zealand (International) Ltd*[745] was not so straightforward, and resulted in a defended hearing. While initial analysis of Honey New Zealand's royal jelly products showed them to have about 4.27% of the labelled quantity of 10HDA,[746] a combination of misinformation and subsequent testing showed this to be erroneous, and due to systemic problems

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[738] *Commerce Commission v John Graham Godwin and Anor*, above n 161.
[739] At [3] and [24].
[740] See discussion on remedies and the need for consistency at 7.5.4.
[741] *Commerce Commission v Shim's International Ltd* Auckland DC, CRI-2009-004-1844, 27 May 2010; *Commerce Commission v NZ Korea Health Ltd* Auckland DC, CRI-2009-004-18035, 29 September 2010; *Commerce Commission v Natural Care Products Ltd* Auckland DC, CRI-2009-004-18045, 4 May 2010; *Commerce Commission v Honey New Zealand (International) Ltd* DC Auckland CRN-2009-004-504773, 27 May 2011.
[742] *Commerce Commission v NZ Korea Health Ltd*, above n 741.
[743] The key active ingredient in royal jelly is 10-hydroxy-2-Decenoic Acid (10HDA), and this is usually the measure of potency which is included on the label or in marketing materials to indicate quality and strength of the product. Commerce Commission "Another company fined for misleading representation of royal jelly" (press release, 30 May 2011).
[744] Institute of Environmental Science & Research Ltd "ESR Final Report" (8 December 2008) PHA09188/09181-09187 at (Obtained under Official Information Act 1982 Request to the Commerce Commission), at 2; Institute of Environmental Science & Research Ltd "Validation of 10-HDA (10-hydroxydecenoic acid) in Royal Jelly products by HPLC" (1 April 2009) 2478000/2478013 at (Obtained under Official Information Act 1982 Request to the Commerce Commission).
[745] *Commerce Commission v Honey New Zealand (International) Ltd*, above n 741.
[746] At [31].

with the testing, the CC dropped the charge under s13(a) with respect to the quantity of 10HDA,[747] and instead proceeded with the charge under s13(j) on country of origin labelling.[748] These cases demonstrate the rather burdensome logistical operation which must take place in order for the CC to prosecute for anomalous levels of the advertised product, and the fact that even once this has occurred, prosecution on this basis is neither a sure-thing, nor is it likely to have substantial effect on the industry as a whole. These problems are endemic to a technical, effectively unregulated industry, and there is little sign of relief on the horizon.[749]

Much like the Honey cases discussed above, *NZ Nutritionals* was prosecuted under s13(j) for its misleading representation of its place of origin on both the powder and the tablets, as previously discussed. NZ Nutritionals defended the case, arguing that due to the combing the imported ingredients, and packaging occurring in NZ, the phrase 'New Zealand made' was not misleading; an argument which ultimately failed in the HC.[750]

One final case which bears mention in relation to s13, and specifically to its application to MMS, is *CC v Ecoworld New Zealand Ltd*.[751] In this case, Ecoworld sold a variety of water treatment products, including the unit in question in this case which is described as follows: "…water is treated in a secret process which permanently energises the water by using vibrational frequencies… this treated water possesses unique and beneficial qualities...".[752] The material then represents that the water creates aerobic conditions in which pathogens and parasites cannot survive, it gives health benefits due to resonance with the cosmos, and helps the body detoxify, improving circulation and blood pressure

[747] At [41]-[42].
[748] At [1].
[749] See also the related case of *Commerce Commission v Topline International and Jeffrey Bernard Cook* [2017] NZDC 9221, where the Commerce Commission took action against a company and director for labelling bee pollen products as being from New Zealand when the entire product and manufacturing process was conducted in China. While this case was charged under s10, and is unrelated to the present issues, it demonstrates the recent direction and focus of the Commerce Commission's activities with regards to checking misleading and deceptive behaviour around food, medicinal and CAM products more broadly.
[750] *Commerce Commission v New Zealand Nutritionals (2004) Ltd*, above n 667, at [1]-[2], and [7]-[10]. It is worth noting as a brief addendum that the Consumers' Right to Know (Country of Origin of Food) Bill 2016 (231-1), currently before Parliament seeks to change the law with regards to single component foods. While the proposed penalties in the Bill show promise for taking actions under primary legislation rather than the FTA, it has a long way to go before it is law, and furthermore, it is unclear whether the Bill will have the scope to cover products like those in the Honey cases, or goats' milk powder and tablets in the present case.
[751] *Commerce Commission v Ecoworld New Zealand Ltd* DC Hamilton CRI-2003-019-21957, 26 July 2005; *Ecoworld New Zealand Ltd v Commerce Commission* [2006] DCR 716 (HC).
[752] At [5].

and reducing allergies.[753] Action was taken solely under s13(e) FTA, and criminal liability was established.

7.5.4 Remedies

Once again, all the cases discussed above resulted in findings of criminal liability under s40, with the CC establishing the misleading and deceptive conduct beyond reasonable doubt. A more detailed analysis of the decisions is ultimately irrelevant, as the penalties are entirely fact dependent, and it offers little by way of further analysis or analogy to the example of MMS.

7.5.5 Application to MMS

There is no doubt that two subsections of s13 are applicable to MMS and would almost certainly yield a decision against the company. Subsection (a) on the composition of the goods, and subs(e) on the performance, characteristics, uses or benefits of the goods would both apply to MMS.

All the requirements of an action under s13 would be present in such a case, with NZ Water Purifier Ltd being in the trade of supplying goods, while the MMS website is engaged in the promotion, and arguably supply through the associated NZ Water Purifier website. The representations do appear to be misleading, especially when the audience to whom they are targeting is considered; vulnerable, desperate people often with serious, terminal or incurable medical conditions. Finally, MMS would likely fall within the scope of subs(a) for the misleading representations that the goods "…have a particular history or particular previous use" or subs(e) for the misleading representations that the goods have "…performance characteristics… uses, or benefits".[754] There would be no doubt in a case like this that the statements on the MMS website are representations, leaving the logical course of action to present charges under both s10 and s13 on the basis of both conduct and representations, as was done in *Zenith* and *Erdic.*

7.6 Defences for MMS

There are three factors which might potentially affect the liability of MMS under the FTA. Those are the presence of the disclaimer on the MMS website, the fact the testimonies on the MMS website are purportedly from third parties, and the proximity, or lack thereof, between MMS and the NZ retailer of the MMS products, NZ Water Purifier.

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[753] At [5].
[754] Fair Trading Act 1986, s13(a) and (e).

7.6.1 Disclaimers

Every page on the MMS website contains the same disclaimer, at the very bottom of the page in small font and an indistinct colour.[755] While this disclaimer does not seek to contract out of the FTA, it does endeavour to avoid all liability for therapeutic statements on the website by breaking the chain of causation between any misleading or deceptive statements and the loss suffered. It does this by making it clear that the reader should not be relying on these statements, but instead should be forming their own opinion as to therapeutic benefits.

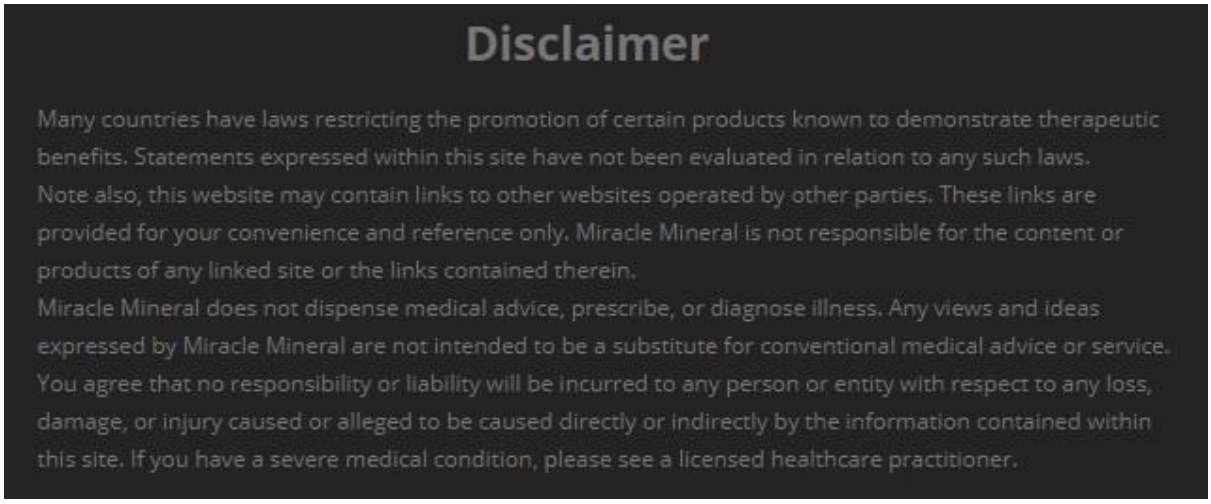

Figure 7.1: MMS Disclaimer, as displayed on www.miraclemineral.co.nz (accessed 21 October 2017)

Ultimately, the use of such a disclaimer is unlikely to be sufficient to avoid responsibility for misleading representations and conduct for two reasons. Firstly, *Medical Benefits Fund of Australia Ltd v Cassidy*[756] established that "…to be effective, the qualifying material must not only be sufficiently prominent, but also sufficiently instructive to nullify the risk that the primary claim might mislead or deceive."[757] The disclaimer on the MMS website is unlikely to meet either of these criteria, firstly, because it is not prominent, being displayed at the bottom of the webpages, often far removed from the therapeutic statements, in a faint, low contrast font. To be effective, disclaimers must be "…reasonably brought to the attention of the purchaser",[758] and small print,[759] illegible text,[760] or a lack of direction to the disclaimer are likely to make a disclaimer ineffective.[761] It is also unlikely to

[755] Grenon, above n 611; see Figure 7.1.
[756] *Medical Benefits Fund of Australia Ltd v Cassidy* [2003] FCAFC 289, (2003) 205 ALR 402.
[757] Gault, above n 657, at [FT9.32(5)].
[758] Lindsay Trotman and Debbie Wilson *Fair Trading: Misleading or Deceptive Conduct* (2nd ed, LexisNexis, Wellington, 2013), at [9.42].
[759] *ACCC v Signature Security Group Pty Ltd* [2003] FCA 3, (2003) ATPR 41-908.
[760] *Lezam Pty Ltd v Seabridge Australia Pty Ltd* (1993) 35 FCR 535, 107 ALR 291.
[761] *George Weston Foods Ltd v Goodman Fielder Ltd* [2000] FCA 1632, (2000) 49 IPR 553, *Abundant Earth Pty Ltd v R & C Products Pty Ltd* (1985) 7 FCR 233, 59 ALR 211.

meet the 'sufficiently instructive' criteria, as it does not actively disavow the therapeutic statements, or even claim they are opinion, but rather states that some countries restrict "…the promotion of certain products known to demonstrate therapeutic benefits",[762] and its statement about medical advice and diagnosis does not address the misleading and deceptive material as to the purported curative effect of the MMS products.

Secondly, the HC of Australia has established the principle that the 'dominant message' is an important factor in weighing whether the conduct is misleading or deceptive.[763] This position has been adopted by the NZ CA in application to ss9 and 13(i) FTA in *Godfrey Hirst NZ Ltd v Cavalier Bremworth Ltd*.[764] In that case, the Court identified five key principles around misleading representations:[765]

(a) *Overall impression:* It is the 'dominant message' or 'general thrust' of the advertisement that is of crucial importance.'

(b) *Wrong only to analyse separate effect of each representation* …

(c) *Qualifying information sufficiently prominent?* …

(d) *Glaring disparity* …

(e) *Tendency to lure consumers into error* ...

It is very unlikely that the MMS website meets this high standard with their disclaimer, for similar reasons to those outlined in the preceding paragraph around the *Medical Benefits* case. Additionally, the 'overall impression' of the MMS website is that the products will help with a variety of therapeutic purposes, meaning they will probably be liable for false or misleading conduct or representations.

7.6.2 Testimonials

The issue of testimonials which potentially include misleading or deceptive representations has not yet come before the NZ courts. A similar issue has arisen in Australia, with the ACCC taking action against a number of companies for misleading reviews posted on websites which purported to be from customers when this was not the case.[766] The ACCC subsequently released guidelines on online reviews for industry, which note that a company may be responsible for posting or publishing

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[762] Grenon, above n 611.
[763] *Australian Competition and Consumer Commission v TPG Internet Pty Ltd* [2013] HCA 54, (2013) 304 ALR 186; Gault, above n 657, at [FT9.32A].
[764] *Godfrey Hirst NZ Ltd v Cavalier Bremworth Ltd* [2014] NZCA 418, [2014] 3 NZLR 611.
[765] At [59].
[766] Noelia Boscana and Simone Knight "Online testimonials - Are you doing enough to avoid ACCC scrutiny?" (17 February 2014) online, <http://www.minterellison.com/Publications/Online-testimonials-avoiding-ACCC-scrutiny/>; Australian Competition and Consumer Commission *What You Need to Know About: Online reviews - a guide for business and review platforms* (ACCC, online, Canberra, November 2013); see notes therein on Euro Solar and Australian Solar Panel case in 2013, as well as Citymove case in 2011.

misleading reviews.[767] Furthermore, some professions like Chiropractors are specifically prevented from using testimonials in advertisements by law in Australia.[768]

Due to the lack of a legal foundation for handling health testimonials in NZ, it is difficult to determine whether the testimonials on the MMS website would amount to misleading or deceptive conduct, however it is certainly arguable that the company bears responsibility to ensure reviews which are factually inaccurate are not included on the company's website (or that a link is not given to these testimonies on the website) in support of their products.

7.6.3 Proximity

The final issue is whether there is sufficient proximity between the MMS website and NZ Water Purifier Website such that content on the latter could be transmuted to the former. Both *Mega Vitamin* and *Erdic* demonstrate that there would be sufficient proximity in the case of MMS. In *Mega Vitamin*, a pamphlet which discussed the multi-vitamin was sufficiently proximate, and in *Erdic*, claims on a variety of distantly related websites were sufficient to support the case. Based on these cases, the specific links on the MMS website to the NZ Water Purifier website will likely be sufficient to enable a breach of s13 to be proven. It has already been suggested that the disclaimer which attempts to avoid any relationship between linked websites will be unlikely to be successful. It could also be noted that a mere conduit defence under s44 will probably be unavailable on the basis that the MMS website actively makes representations about the products in question.[769]

7.7 Section 12A FTA

7.7.1 Overview

Section 12A FTA is a new addition to the Act[770] which focuses on the making of unsubstantiated representations.[771] Included in the Act in 2014,[772] s12A is relatively untested,[773] and due to a stark difference in application to a similar section in Australia,[774] it is not possible to analogise the position

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[767] Australian Competition and Consumer Commission, above n 766, at 4 and 7.
[768] Health Practitioner Regulation National Law Act 2009 (NSW), s133. There is a possibility of similar restrictions coming into NZ, in the wake of a recent study showing 35% of chiropractors' websites contained health testimonials; Mark Hanna and Mark Honeychurch "Chronic misleading online advertising by chiropractors" (2016) 129(1432) New Zealand Medical Journal 91, at 92.
[769] See Gault, above n 657, at [FT9.30] for a list of cases where a similar situation has arisen, and the defence of 'mere conduits of information' has failed.
[770] Inserted by the Fair Trading Amendment Act 2013.
[771] Fair Trading Act 1986, ss9-12 focus on conduct, while ss12A-14A focus on representations.
[772] Fair Trading Amendment Act 2013, s10.
[773] As at the time of writing, there had been only one case, and one warning under s12A; see 7.7.3.
[774] In Australia, the similar section is an evidentiary provision only, and not a separate offence as it is in New Zealand.

NZ will take. Nevertheless, s12A is likely to be a vital tool in preventing unsubstantiated representations, and could form a basis for many actions against CAM products.[775] A breach of s12A in NZ can be a basis for the CC[776] commencing either civil or criminal proceedings.[777]

7.7.2 Elements of s12A

Section 12A requires that a person who is in trade, makes a representation as to goods or services or their promotion, and that this representation be unsubstantiated.[778] Section 12A(2) employs a relatively standard definition of 'unsubstantiated', which simply requires that the person making the representation has no reasonable evidential basis for the claims, regardless of its veracity, or false or misleading nature.[779] It should also be noted that s12A(3) provides a puffery defence to this section, which applies where a reasonable person would not expect the representation to be substantiated.

7.7.3 Cases

So far, there have been few cases under s12A,[780] and none which dealt with CAM products. One relevant example is that of Baa Baa Beads. In 2015, Baa Baa Beads were issued a warning letter by the Commission about a failure to substantiate claims of the healing properties of their amber necklaces.[781] These claims included statements that "Succinic acid 'strengthens the body, improves immunity'", and "Succinic acid has been 'proven' to be 'the equal or better of many commercial drugs…'" [782] No further action was taken, as the company amended their representations in

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[775] Fair Trading Act 1986, s12A; "Unsubstantiated representations
(1) A person must not, in trade, make an unsubstantiated representation.
(2) A representation is unsubstantiated if the person making the representation does not, when the representation is made, have reasonable grounds for the representation, irrespective of whether the representation is false or misleading.
(3) This section does not apply to a representation that a reasonable person would not expect to be substantiated.
(4) In this section and sections 12B to 12D, representation means a representation that is made-
(a) in respect of goods, services, or an interest in land; and
(b) in connection with-
(i) the supply or possible supply of the goods or services; or
(ii) the sale or grant or possible sale or grant of the interest in land; or
(iii) the promotion by any means of the supply or use of the goods or services or the sale or grant of the interest in land.

[776] At s12C; "Limitation on commencement of proceedings in relation to unsubstantiated representation" under this section, only the Commerce Commission can commence proceedings under s12A.

[777] At s12C; "Limitation on commencement of proceedings in relation to unsubstantiated representations Despite anything to the contrary in Part 5, only the Commission may commence proceedings, apply for an order, or apply for an injunction in relation to a contravention of section 12A."

[778] At 12A(1).

[779] At s12A(2). Gault, above n 657, at [FT12A.04].

[780] *BN Global Trading Ltd v Broadtrust Group Ltd* [2016] NZHC 987; *Real Estate Agents Authority v Domb* [2017] NZCA 199, [2017] NZAR 871; *Commerce Commission v Fujitsu General New Zealand Ltd* [2017] NZDC 21512.

[781] Commerce Commission "Baa Baa Beads warned over health claims" (press release, 6 November 2015).

[782] At 1.

consultation with the Commission. The CC did however make an important statement with respect to the evidence sufficient to substantiate such representations:[783]

> Whether the claim is express or implied, businesses should only make claims based upon facts, figures and credible sources of information that support their accuracy. Traders cannot simply rely on general information they find in books and online.

This statement appeared to include 'traditional' evidence of healing properties.

More recently, the heat pump company Fujitsu were fined for unsubstantiated representations under s12A in the first case of its kind in NZ.[784] A number of unsubstantiated representations were made about heat pump performance over an extended period, and the Judge found it material in sentencing that "…consumers or potential consumers are unable, through any reasonable means to test the accuracy of these claims."[785] This may be significant for the future use of s12A, in cases involving unsubstantiated representations on CAM products, were consumers are at a similar disadvantage to testing the efficacy of CAM products, or veracity of the claims made thereon.

7.7.4 Application to MMS

Section 12A is an invaluable tool for the CC, especially under current regulations where there are a multitude of CAM products making TCs, and insufficient resources to investigate all of them. The CC can require the maker of a TC to substantiate the claim under threat of civil or criminal liability. Alternatively, through warning letters under s12A as given to Baa Baa Beads, the Commission could address a wide number of unsubstantiated health claims, subsequently determining which to take further action upon if the warning did not result in substantiation or removal of TCs.

In application to MMS, s12A is the most appropriate section considered in this Chapter. It has been established that the MMS website makes representations,[786] leaving the question of whether these are unsubstantiated. On first glance, it appears that these representations are supported by evidence, with a note on the website's homepage "Chlorine Dioxide is a scientifically proven pathogen killer…",[787] followed by a series of links to government papers, journal articles and other materials which are claimed to provide scientific proof. However, upon thorough analysis, none of these sources relate to MMS, nor show anything but the general, and well accepted ability of chlorite as a water

[783] At 1.
[784] *Commerce Commission v Fujitsu General New Zealand Ltd*, above n 780; Commerce Commission "Fujitsu fined $310,000 in Commerce Commission's first unsubstantiated claims case" (press release, 20 September 2017).
[785] At [62].
[786] See discussion on MMS and s13 FTA at 7.5.5.
[787] Grenon, above n 611.

sterilant.[788] This certainly does not meet the Commission's standard for substantiation of "…claims based on facts, figures and credible sources of information that support their accuracy."[789]

The CC could therefore issue a warning letter, accept enforceable undertakings, or alternatively commence civil or criminal proceedings.

7.8 Concluding remarks to the Fair Trading Act

Sections 9, 10, and 13 FTA provide valuable and well-tested means of enforcement against misleading conduct and representations. Section 12A enables a more preventative approach to unsubstantiated representations, with the option of taking action under this section if necessary.

In application to misleading or deceptive conduct around CAM products, s12A is a good starting point if the product is making unsubstantiated representations, but ss10 and 13 will usually be the most

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[788] At 1; all references on the MMS website were analysed and brief reasons for their dismissal as relevant, supporting or sound scientific evidence follow:
Centre for Disease Control and Prevention "A Guide to Drinking Water Treatment and Sanitation for Backcountry and Travel Use" (10 April 2009) <https://www.cdc.gov/healthywater/drinking/travel/backcountry_water_treatment.html>; the CDC website contains a wealth of information on water sterilisation with chlorine dioxide, but nothing whatsoever on MMS or use of chlorine dioxide for therapeutic purposes.
Judith R. Lubbers, Sudha Chauan and Joseph R. Bianchine "Controlled Clinical Evaluations of Chlorine Dixoide, Chlorite and Chlorate in Man" (1982) 46 Environmental Health Perspectives 57; this is frequently cited by MMS proponents as the seminal paper corroborating its use, however the paper used a lower dose of chlorite than most of the MMS methods, and more importantly, used a vastly different procedure, with multiple days between giving patients the dose. Finally, this was a relatively small clinical trial, which has not been repeated.
MMS Testimonials LEAKED: Proof the Red Cross Cured 154 Malaria Cases with MMS; this video is obviously insufficient evidence for s12A FTA, and furthermore, the International Federation of Red Cross and Red Crescent Societies has dissociated themselves from any relation to the video, and purported 'clinical trials', see International Federation of Red Cross and Red Crescent Societies "IFRC strongly dissociates from the claim of a 'miracle' solution to defeat malaria" (press release, 15 May 2013).
Norio Ogata and Takashi Shibata "Protective effect of low-concentration chlorine dioxide gas against influenza A virus infection" (2008) 89 Journal of General Virology 60; the study in this article sprayed chlorine dioxide gas into the air at the same time as influenza A virus to determine the effects on mice. This was extremely effective at preventing influenza in the mice when sprayed concurrently, but when sprayed 15 minutes later it was completely ineffectual, suggesting its mode of action was an aerosol one before ingestion, and thus showing no relationship whatsoever to MMS or its purported mode of action.
Frederich W. Kuhne, Michael McGrath and Edgar G. Engleman Use of a Chemically-stabilized Chlorite Solution for Inhibiting an Antigen-specific Immune Response; while this patent appears to show an antigen response for use of chlorite solution, the clinical data and dose data is varied, with only one clinical trial in humans with a very low number of participants.
A. Rubinstein, T. Chanh and DB Rubinstein Chlorine dioxide sterilization of red blood cells for transfusion, additional studies; not only did these experiments show incomplete activation by chlorine dioxide, they also used a process for treating red blood cells which is in no way comparable to the MMS procedures.
Thomas Lee Hesselink "On the Mechanisms of Toxicity of Chlorine Oxides against Malarial Parasites: An Overview" (6 September 2007) <http://bioredox.mysite.com/CLOXhtml/CLOXprnt+refs.htm>; this is a non-peer reviewed website article by a proponent of MMS.
[789] Commerce Commission, above n 781.

effective. The majority of case law involving CAM products under the FTA has been taken under these two sections, commonly argued together in the alternative. Section 10 relates specifically to goods, involves a lower standard with 'liable to mislead', than s9's 'likely to mislead', and like s13, also enables criminal sanctions, as well as civil remedies in the event of breach. Section 13 deals more specifically with representations, focusing on particular kinds of representations which may facilitate more targeted enforcement.

Despite the applicability of the FTA, and ready means of action against misleading or deceptive CAM products through the consumer protection arm of the CC, this reliance on the FTA has a downside. The litigation of almost all cases involving CAM products under the FTA demonstrates the unenforceable and toothless nature of primary provisions like the DSRs. CAM product regulations should prevent such misleading and deceptive practices in the first place, and failing that, provide enforcement measures when products or suppliers breach those regulations, with the FTA being a backstop for consumer protection where all else fails. However, the DSRs have failed to regulate in this way, and the structure of the NHSPB looks set to make a similar mistake.

7.9 The Consumer Guarantees Act 1993

The CGA was enacted to provide some protection for consumers from businesses and suppliers to address the possible power imbalance. The Act defines a 'consumer' as a person who obtains goods or services, ordinarily acquired from a supplier for "…personal, domestic, or household use or consumption",[790] providing they do not acquire them for any commercial purpose.[791] It provides a number of guarantees for 'consumers' as to goods and services, with specific remedies in the event that these guarantees are not upheld or adhered to by companies.[792] Two of these guarantees are potentially relevant to the CAM products.

With respect to goods, the Act provides consumers with guarantees that they are 'reasonably safe', 'fit for purpose', and 'of an acceptable quality'.[793] Where there is a breach of these guarantees, the consumer broadly has two remedies against the supplier. They may require the supplier to remedy

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[790] Consumer Guarantees Act 1993, s2(1), 'consumer' (a).
[791] At s2(1), 'consumer' (b).
[792] At s1A. A consumer broadly has two remedies against a supplier. They may require the supplier to remedy the problem within a reasonable time, which usually amounts to a repair, replacement or refund, with the choice reverting to the consumer if the fault is not remedied within a reasonable time. Alternatively if the failure cannot be remedied or is of a substantial nature, the consumer may obtain damages from the supplier, which extends to damages for reasonably foreseeable loss resulting from the goods' failure. Similar remedies apply in certain circumstances against the manufacturers of the goods; at ss18, 19, 25 and 27.
[793] At s1A.

the problem within a reasonable time,[794] which usually amounts to a repair, replacement or refund,[795] with the choice reverting to the consumer if the fault is not remedied within a reasonable time.[796] Alternatively, if the failure cannot be remedied or is of a substantial nature, the consumer may obtain damages from the supplier,[797] which extends to damages for reasonably foreseeable loss resulting from the goods' failure.[798] Similar remedies apply in certain circumstances against the manufacturers of the goods.[799]

7.9.1 Sections 6 & 7: Acceptable quality

Section 6 CGA provides that goods supplied to consumers come with a guarantee that they are of an acceptable quality. Where this is not the case, consumers have a right of redress against the supplier or manufacturer under Part 2 or 3 CGA respectively.[800]

Section 7 provides detail on what 'acceptable quality' entails, listing five criteria: goods must be fit for all purposes for which they are commonly supplied, have an appropriate appearance and finish, be free from defects, safe, and durable.[801] In outlining the meaning of 'acceptable quality' for the purposes of s6, s7(1) goes on to note matters to which the reasonable consumer may have regard when determining whether the goods are acceptable. In an echo of the FTA, this includes; "…the nature of the goods,"[802] any statements on the packaging or label,[803] and any representation about the goods.[804] It is important to note the similar objective standard which applies to 'acceptable quality' here through the 'reasonable consumer'.

There is a lack of reported cases which address CAM products under the CGA, due to the requirement that the consumer bring the action in such a case, as well as the associated difficulty incumbent upon the plaintiff to demonstrate that the CAM product is not of acceptable quality. While it is thus difficult to demonstrate the application of the CGA to CAM products, one Australian case raises an important consideration. In *Carey-Hazell v Getz Bros Co*,[805] it was held that safe, or 'free from defect' was a

[794] At s18(2).
[795] At s19(1).
[796] At s18(2)(b).
[797] At s18(3).
[798] At s18(4).
[799] At ss25 and 27.
[800] At s6.
[801] At s7(1).
[802] At s7(1)(f).
[803] At s7(1)(h).
[804] At s7(1)(i).
[805] *Carey-Hazell v Getz Bros & Co (Aust) Pty Ltd* [2004] FCA 853, [2004] ASAL 55-130.

different standard to free from risk, and did not have the same implications.[806] Consequently, the fact that the plaintiff's heart valve encountered issues, as happened to a minority of people who received them, did not mean the valves were unsafe.[807] In relation to CAM products, this might mean that an adverse interaction with another product, or reaction of a CAM product with an underlying medical condition would not be the fault of the supplier or manufacturer, providing the CAM product was 'free from defect'.

7.9.2 Section 8: Fit for purpose

Section 8 generally provides a guarantee as to the fitness of goods supplied to a consumer for a particular purpose. This encompasses any purpose which the consumer expressly makes known to the supplier,[808] or any more general purpose for which the supplier represents that the goods are fit.[809] Section 8(c) creates exceptions if the consumer is not relying on the supplier's skill or judgement,[810] or where it would be unreasonable for the consumer to rely on that skill or judgment.[811]

There is an important distinction between s7 and s8. Section 7 guarantees fitness for a common purpose, while s8 guarantees fitness for a particular purpose, which the purchaser makes known to the supplier. Section 8(3)[812] applies to both common and particular purpose, but importantly, s7 only applies to fitness for a common purpose.[813]

The question remains of how fitness for purpose, or s8 more generally relates to CAM products. More relevant in this context is the idea of a common purpose, and therefore s6 and 7 are also pertinent here. While a particular purpose will arise where consumers are taking advice from the retailer of the product or practitioner on their particular condition, this is probably a less common occurrence, and is outside the scope of this thesis. On the basis of fitness for common purpose, a supplier will need to ensure the CAM product is fit for any reasonable purpose for which the goods may be used. This will certainly extend to any claims of performance like TCs or HBCs displayed on the label or associated with the product. As such, if a container of Olive Leaf, for example, stated on the label 'relieves cold

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[806] Gault, above n 657, at [CG7.09(5)]. The case was brought under the Trade Practices Act 1974 (Cth), ss75AD, 75AC, and 74B.
[807] At [CG7.09(5)].
[808] Consumer Guarantees Act 1993, s8(1)(a).
[809] At s8(1)(b).
[810] At s8(2)(a).
[811] At s8(2)(b).
[812] At s8(3); "This section applies whether or not the purpose is a purpose for which the goods are commonly supplied."
[813] Gault, above n 657, at [CG7.04].

symptoms', it would be likely that the reasonable consumer could expect the product to do just that.[814] In the event it did not do so, the issue would be establishing that fact; an onus which rests on the consumer, and is one of the principal problems with using the CGA for these types of products.

7.9.3 Application to MMS

As previously noted, the CGA could be used if a 'consumer' who had purchased MMS claimed it was not of acceptable quality or not fit for purpose.

First, the purchaser must meet the definition of consumer; namely that they are acquiring goods, which are ordinarily acquired for a personal or household use or consumption. Then, one of the guarantees must be breached. An argument that MMS is not of an acceptable quality could be based on the fact that it is not safe to be consuming chlorine dioxide,[815] as the MMS website directs consumers.

Alternatively, the consumer could argue that the product was neither fit for a particular nor common purpose. The MMS website, which directs consumer to the NZ Water Purifier site, contains specific information on the manner in which MMS has relieved numerous specific medical conditions in the form of testimonies, which is arguably tantamount to advice on the suitability of the product for a particular purpose. However, particular purpose must be made known to the vendor by the purchaser, and it is unlikely that a particular purpose will usually work when one is ordering online. The stronger argument would be that MMS is not fit for common purpose. In one fell swoop, this annuls any argument from NZ Water Purifier that the goods are not supplied for a therapeutic purpose,[816] and also facilitates an argument that the goods are not fit for that purpose, as they do not have the therapeutic effect outlined on the MMS website.

Despite the fact that a claim against MMS is plausible under the CGA, there remain problems with such a claim. Firstly, MMS and its website is neither the supplier nor manufacturer, and unless their representations can be transmuted to NZ Water Purifier, the basis for a claim of acceptable quality of fitness for purpose is tenuous. Furthermore, not only does a consumer need to bring the action and prove the elements, the remedy comes in the form of resolution for that particular consumer, rather than broad penalties aimed at disincentivising the kind of conduct MMS exhibits. The consumer bears the onus to substantiate the fact that the goods are not fit for purpose or of acceptable quality, and

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[814] See this example of Olive Leaf and more discussion on its label at Chapter 9.
[815] Consumer Guarantees Act 1993, s7(1)(d).
[816] At s8(3); "This section applies whether or not the purpose is a purpose for which the goods are commonly supplied."

this poses an onerous burden upon consumers, highlighting the root of the problem with applying the CGA to CAM products; namely that it is not worth a consumer's while to take such an action, especially when the price of the goods is considered, but rather they are better protesting with their wallets.[817]

7.10 Concluding remarks to the Consumer Guarantees Act

There is certainly scope for an action against a CAM product within ss6 and 7 CGA on acceptable quality, and s8 that goods be fit for purpose, but the problem facing an action against a CAM product under the CGA is the practicalities. Such an action must be brought by a consumer, and they will be faced with the logistical difficulty of demonstrating that the goods are either not of an acceptable quality, or are not fit for purpose. Due to the low value of CAM products, coupled with the difficulty in determining the actual effect of the product, an action by a consumer under the CGA is relatively unlikely, with consumers being more prone to merely protest with their wallet and not purchase a particular CAM product again.[818]

7.11 Conclusion

It is evident from the variety of cases discussed in this Chapter that the FTA is potentially effective at dealing with misleading or deceptive conduct in relation to CAM products. Conversely, the CGA does not provide the same scope for such action; in large part due to the requirement that consumers bring actions under the CGA, in contrast to the CC's ability to bring FTA actions.

The question remains whether the FTA's role in addressing misleading and deceptive practices with CAM products is appropriate. Certainly it is necessary, especially when primary legislation like the FA, MA and DSRs are ineffective in addressing these problems, but it would appear that an enforceable mechanism in the primary legislation which prevents and penalises the presence of misleading or deceptive conduct and representations would be more appropriate.

This is particularly important in light of the CC's stance that it does not view its role as the judge on the efficacy of CAM.[819]

The MMS case study has suggested that while the FA, MA and DSRs will struggle to deal with MMS, the FTA could potentially address the problems associated with MMS under a number of different civil or criminal provisions. It is difficult to determine whether a case against MMS could be established

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[817] Tokeley, above n 343, at 430.
[818] At 430-431.
[819] Commerce Commission "Health and nutrition claims" (29 October 2015) <www.comcom.govt.nz/>.

beyond reasonable doubt, but it is almost certain that it could be on the balance of probabilities. Technical questions as to the effect of the separation between the websites, and whether testimonies and the equivocation on the effect of the product are tantamount to TCs or misleading and deceptive conduct require further consideration.

With an appreciation for the role of consumer protection legislation as it currently applies to CAM products, the next Chapter now turns to consider an even broader issue affecting the regulation of CAM products in NZ; the Treaty of Waitangi and the place of traditional medicine and the Wai 262 report in CAM product legislation.

8 The Treaty of Waitangi & the Wai 262 Report

8.1 Introduction

A review of existing legislation, and a proposal to design new legislation in NZ, would be incomplete without consideration of the Treaty of Waitangi and the principles therein. This is even more essential when the subject matter encompass Māori TM and the possibility of its regulation under CAM product legislation.

As noted in Chapter 1, rongoā Māori is an holistic healthcare system, which includes rakau rongoā; a form of herbal medicine. Like many forms of traditional herbalism, it is likely that many of the remedies used as part of rakau rongoā contain active ingredients with a pharmacological basis, although there has been insufficient research to conclusively determine either the efficacy or toxicity of these remedies to date.[820]

In the context of rongoā, this Chapter will consider the prominence, or lack thereof, of the principles of the Treaty of Waitangi in existing and proposed CAM product regulation in NZ. The Chapter will then turn to review the Wai 262 Report, and specifically the recommendations around rongoā, with a view to the adoption and implementation of these, where possible, in the proposal.

8.2 The Treaty of Waitangi

Te Tiriti o Waitangi (The Treaty of Waitangi) has a defining role in NZ's constitutional history, and any discussion on CAM regulation, let alone rongoā Māori, would be incomplete without a consideration of the Treaty and its principles. Importantly for the NHSPB, and any other proposed CAM product legislation, it must satisfy the Legislation Design Committee Guidelines,[821] as well as Cabinet,[822] that the Bill is not inconsistent with the principles of the Treaty of Waitangi.[823]

The principles of the Treaty are one of the cornerstones of NZ's unwritten constitution. In the spirit of partnership required by the Treaty, there are seven general guidelines regarding the effect of the legislation upon the Treaty which should be considered, where applicable, in the drafting of new legislation. [824] Broadly, these require identification of affected Māori interests, consultation,

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[820] Te Papa, above n 23.
[821] Cabinet Office *Cabinet Manual 2017* (2017), at [7.23].
[822] Department of the Prime Minister and Cabinet "Template for a paper seeking agreement to introduce a bill" (27 July 2017) at [10].
[823] Legislation Design and Advisory Committee *LAC Guidelines 2014 edition: Chapter 4 The Treaty of Waitangi and Treaty settlements* (online ed, LDAC, 19 December 2014), at 17-19.
[824] At 17-19.

consideration of additional measures in the event of conflict, informed decision making, no inconsistency with existing Treaty settlements, and where legislation is intended to be inconsistent with the principles of the Treaty, then clear language must be used.[825]

To appreciate the principles of the Treaty and the relationship of modern legislation with the Treaty, it is necessary to briefly consider the history of the Treaty of Waitangi.

8.2.1 A history of the Treaty

The Treaty was drafted and signed by many key stakeholders in 1840. On the behest of Lieutenant-Governor William Hobson, James Busby and others drafted the original English version of the Treaty, which was subsequently translated into Māori by missionaries Henry and Edward Williams.[826] Herein lie many of the ensuing problems with the Treaty, stemming from a translation which failed to construe the same meaning between the English and Māori versions of the Treaty.

The two versions of the Treaty were available for signature at Waitangi on February 6 1840, then travelled throughout the Country,[827] collecting the signatures of 500 chiefs. The Colonial office later declared that the Treaty applied to all Māori, regardless of whether they had signed it or not.[828]

8.2.2 Article 2

The following is a recent translation of the Māori text of Article 2 into English, in order to appreciate some of the problems arising from the translation, especially insofar as they affect traditional medicine.[829]

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[825] Legislation Design and Advisory Committee *LAC Guidelines 2014 edition: Checklist for officials* (online ed, LDAC, 16 February 2015); the seven principles which Ministers must have regard insofar as the Treaty of Waitangi is concerned are as follows:

4.1 Māori interests that will be affected by the proposed legislation should be identified.

4.2 New legislation must not be inconsistent with an existing Treaty settlement.

4.3 Any land, bodies of water or other resources potentially subject to customary title (or rights), and that might be affected by proposed legislation, should be identified.

4.4 The Government must make informed decisions where legislation will affect, or have the potential to affect, the rights and interests of Māori.

4.5 Consultation must target Māori whose interests are particularly affected.

4.6 When legislation has the potential to conflict with the rights or interests of Māori under the Treaty, additional measures should be considered to ensure recognition of the principles of the Treaty or the particular rights concerned.

4.7 Clear language is required where legislation is intended to be inconsistent with the principles of the Treaty.

[826] Ministry for Culture and Heritage "The Treaty in brief" (17 May 2017) NZ History <www.nzhistory.govt.nz/>.

[827] There were eight further copies of the Treaty upon which a total of 500 chief's signatures were collected.

[828] Ministry for Culture and Heritage, above n 826.

[829] Waitangi Tribunal "Translation of the te reo Māori text" (19 September 2016) <www.waitangitribunal.govt.nz/>. Compare with the original English version of Article 2 at fn 833.

> The Queen of England agrees to protect the chiefs, the subtribes and all the people of New Zealand in the unqualified exercise of their chieftainship over their lands, villages and all their treasures. But on the other hand the Chiefs of the Confederation and all the Chiefs will sell land to the Queen at a price agreed to by the person owning it and by the person buying it (the latter being) appointed by the Queen as her purchase agent.

Two major problems arose from the translation and the promises made to Māori at Waitangi that are relevant to this discussion; namely the principles of sovereignty and full authority over taonga, or treasures.[830] Where the English version of the Treaty notes cession of sovereignty to the Crown,[831] the Māori version used the term *kawanatanga*, which is more akin to British governance over their land while they could maintain sovereignty.[832] Similarly, the original English version[833] promised Māori 'full, exclusive and undisturbed possession' over their lands, forests, fisheries and other goods, while the Māori version of the Treaty promised *tino rangatiratanga* over *taonga*,[834] which is generally considered to be full authority over all their treasures, tangible or intangible.[835] The level of protection guaranteed under the Treaty to rongoā, as taonga, is therefore unclear.

8.2.3 The Treaty & CAM product legislation

The use of rongoā in NZ has something of a torrid history. Many years prior to the DSRs, the Tohunga Suppression Act prohibited the practise of rongoā at risk of fine or imprisonment.[836] Nine convictions occurred under the Act,[837] before its repeal in 1962.[838]

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[830] Taonga is defined as "property, goods, possession, effects, object" and more specifically, as "treasure, anything prized - applied to anything considered to be of value including socially or culturally valuable objects, resources, phenomenon, ideas and techniques"; Māori Dictionary "Taonga" (2017) <www.maoridictionary.co.nz/>.

[831] Ministry for Culture and Heritage "Read the Treaty" (1 February 2017) <www.nzhistory.govt.nz/>; at Article 1:

"The Chiefs of the Confederation of the United Tribes of New Zealand and the separate and independent Chiefs who have not become members of the Confederation cede to Her Majesty the Queen of England absolutely and without reservation all the rights and powers of Sovereignty which the said Confederation or Individual Chiefs respectively exercise or possess, or may be supposed to exercise or to possess over their respective Territories as the sole sovereigns thereof."

[832] Waitangi Treaty Grounds "Explore the Treaty" (2017) <www.waitangi.org.nz/>.

[833] Ministry for Culture and Heritage, above n 831; at Article 2:

"Her Majesty the Queen of England confirms and guarantees to the Chiefs and Tribes of New Zealand and to the respective families and individuals thereof the full exclusive and undisturbed possession of their Lands and Estates Forests Fisheries and other properties which they may collectively or individually possess so long as it is their wish and desire to retain the same in their possession; but the Chiefs of the United Tribes and the individual Chiefs yield to Her Majesty the exclusive right of Preemption over such lands as the proprietors thereof may be disposed to alienate at such prices as may be agreed upon between the respective Proprietors and persons appointed by Her Majesty to treat with them in that behalf."

[834] Ministry for Culture and Heritage, above n 826.

[835] Māori Dictionary, above n 830.

[836] Tohunga Suppression Act 1907.

[837] Māmari Stephens "A Return to the Tohunga Suppression Act 1907" (2001) 32(2) VUWLR 437, at 459.

[838] At 444.

Despite the DSRs not referencing rongoā, the MoH has increased its support for this practice, with 19 rongoā practitioners currently funded across NZ,[839] and the collaborative development of a set of standards for the provision of Rongoā healthcare.[840] If concerns were raised about claims or advertising of a rongoā product under the current legislation, it is likely rongoā would be handled as a herbal medicine or related product under the MA.

As mentioned in Chapter 5, the NHSPB avoided mentioning the Treaty, or regulating rongoā; aside from its avoidance to regulate any kind of practitioner who dispenses CAM products.[841] Consequently, it was unlikely that much would have changed with respect to the regulation of rongoā under the NHSPB, unless rongoā products were to be manufactured in a commercial capacity, resulting in the likely application of the NHSPB as it would have applied to any other CAM product.[842]

8.3 Wai 262: The Flora & Fauna Case

The Waitangi Tribunal was created by the Treaty of Waitangi Act 1975 to investigate breaches of the Treaty of Waitangi. The two hundred and sixty-second claim to the Waitangi Tribunal has been described as the most important claim the Tribunal has ever considered,[843] as well as one of the most complex.[844] Brought to the Tribunal in 1991, the claim took 20 years to be completed and the report detailing its recommendations was released in 2011. Despite six years passing since the release of the findings of the Waitangi Tribunal in Wai 262, the government has still not made a formal response to the report or its recommendations, and at the time of writing, no indication was available that the 'whole-of-government' response will ever be forthcoming.[845]

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[839] Ministry of Health, above n 21.

[840] Ministry of Health *Tikanga ā-Rongoā* (Ministry of Health, online ed, Wellington, 2014).

[841] Natural Health and Supplementary Products Bill 2011 (324-2), s13A(a); "Natural health and supplementary products that do not require product notification
Section 13 does not apply to-
(a) any natural health and supplementary product that is made by a practitioner to be administered to a particular person after being requested by or on behalf of that person to use the practitioner's own judgement as to the treatment required;"

[842] (15 September 2011) 675 NZPD 21391; Te Ururoa Flavell MP noted that Māori Party's support for the exclusion of rongoā Māori from the Bill, going further to agree that were rongoā products to be commercially produced, it would fall within the NHSPB's ambit, like any other product.

[843] Toby Mills "Wai 262" (Film, 2006) online, New Zealand <www.nzonscreen.com/>, David Williams, at 4:55.

[844] Waitangi Tribunal "Ko Aotearoa Tēnei: Report on the Wai 262 Claim Released" (2 July 2011) <www.waitangitribunal.govt.nz/>.

[845] See discussions in Barbara Sullivan and Lynell Tuffery-Huria "New Zealand: Wai 262 report and after" (2014) 9(5) Journal of Intellectual Property Law & Practice 403, at 407; Radio New Zealand "WAI 262 response disappointing - Te Rarawa" *Radio New Zealand* (online ed, New Zealand, 18 June 2013); Lee Taylor *Māori Affairs: selected issues* (Parliamentary Library, Parliamentary Library Research Paper, December 2011), at 1.

Ko Aotearoa Tēnei, which translates as 'This is New Zealand' is the Wai 262 Report,[846] and contains wide ranging findings which concern Māori intellectual property rights,[847] rights to the conservation estate, the place of Rongoā Māori in New Zealand,[848] and much in-between. Following an explanation of the Tribunal itself and the background to the Wai 262 claim, this section briefly considers the recommendations in chapter 7 of the Report insofar as it pertains to rongoā in NZ.

8.3.1 The Waitangi Tribunal

The Waitangi Tribunal was created by the Treaty of Waitangi Act 1975 as a permanent commission of inquiry to investigate breaches of the Treaty dating back to 1840.[849] The Tribunal comprises 20 members, the Chairperson at the time of the Wai 262 Report being Chief Judge Williams.[850] The Tribunal may only make recommendations based upon claims brought before it, and these are not binding unless explicitly endorsed by the Courts of New Zealand or implemented by Parliament.

8.3.2 Background to the Wai 262 claim

While on paper the initial claim listed seven plant and animal species,[851] the catalyst for the Wai 262 claim is widely seen to be the sale of ancient, native kumara tubers by a Government science department to a research institute in Japan in the late 1980s.[852] This led to the six original claimants[853] from six iwi[854] drafting and bringing the claim to the Waitangi Tribunal on 9 October 1991. Due to a variety of matters, the final report was not released until nearly 20 years later, on 2 July 2011.[855]

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[846] Waitangi Tribunal, above n 844.
[847] Waitangi Tribunal *Ko Aotearoa Tēnei: A Report into Claims Concerning New Zealand Law and Policy Affecting Māori Culture and Identity* (Wai 262, 2011), at Chapters 1-2.
[848] At Chapter 7.
[849] Treaty of Waitangi Act 1975, s5 sets out the role of the Tribunal. At s6(1)(a); although initially, the Tribunal only consider claims arising after 1975, but this was amended in the 1980s.
[850] Waitangi Tribunal "Members of the Waitangi Tribunal" (29 March 2017) <www.waitangitribunal.govt.nz/>.
[851] These were: Kumara, Pohutkawa, Koromiko, Puwananga, Pupu harakeke, Tuatara and Kereru, as well as all the indigenous forests of Aotearoa; Oliver Sutherland, Murray Parsons and Moana Jackson "The Background to WAI 262" (11, June 2011) online, <www.wai262.weebly.com/>, at 6.
[852] Mills, above n 843; Sutherland, Parsons and Jackson, above n 851.
[853] Sutherland, Parsons and Jackson, above n 851, at 4; the original six claimants were Saana Murray, Del Wihongi, Witi McMath, Tama Poata, Kataraina Rimene, and John Hippolite.
[854] At 9; the six original tribes the claimants represented were; Te Rarawa, Ngāti Wai, Ngāti Kurī, Kahungunu, Te-Whanau-o-Ruataupare/Ngāti Porou, and Ngāti Kōata.
[855] David V. Williams "*Ko Aotearoa Tenei:* Law and Policy Affecting Maori Culture and Identity" (2013) 20 International Journal of Cultural Property 311, at 321; Waitangi Tribunal *Ko Aotearoa Tēnei - Factsheet 2: Intellectual Property in Taonga Works* (Wai 262, online, 2 July 2011), at 1.

The claim is widely referred to by its number in the queue of Waitangi Tribunal claims; Wai 262. However, it is also known as the Flora and Fauna claim.[856] Importantly, two key themes pervade the entire report. The first is the encompassing concept that the report as a whole addresses the place of mātauranga Māori in contemporary New Zealand.[857]

> Mātauranga Māori includes language, science and technology, laws, history, systems of property and value exchange, and rituals and ceremonies. It also includes forms of expression and art forms… But, more fundamentally, it incorporates core Māori cultural values…

For the purposes of this discussion, the most important 'core Māori cultural value', and the second pervasive concept is that of "…kaitiakitanga, or cultural guardianship – the system of law through which iwi and hapū are obliged to nurture and care for taonga."[858]

8.3.3 Chapter 7 *Ko Aotearoa Tēnei* – Rongoā Māori

Chapter seven is unique in that it is the only chapter in the Report which not only looks on historical matters where the findings generally avoid this, but it is the singular occasion where an historical grievance is considered in *Ko Aotearoa Tēnei*; namely the Tohunga Suppression Act 1907.[859]

Three recommendations can be crystallised from the Report in relation to rongoā.[860] Firstly, the Report recommends recognition of the important role of holism in rongoā, with a view beyond efficacy to consider not only the quantifiable medical outcomes, but also its role in mental health and lifestyle choices more broadly.[861] Secondly, a number of points are raised surrounding funding and support for rongoā services within the NZ health sector.[862] This includes the development of rongoā policies between the MoH and other relevant Government agencies like the Department of Conservation, to ensure tohunga have access to rongoā rākau.[863] The third recommendation from the Wai 262 Report was for the collection of empirical data on usage of services and the extent of demand.[864] Cost-benefit analyses tend to indicate the cost of funding such healthcare is seriously outweighed by the savings

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[856] This is despite its eventual scope being much broader than merely flora and fauna, with chapters extending to the place of Te Reo Māori in New Zealand, and the need to comply with the Treaty principles when agreeing to international treaties; Waitangi Tribunal, above n 847, at Chapters 5 & 7.
[857] Waitangi Tribunal *Ko Aotearoa Tēnei - Factsheet 1: Key Themes* (Wai 262, online, 2011), at 1.
[858] At 1.
[859] Williams, above n 855, at 321.
[860] Waitangi Tribunal, above n 847, at 226-228.
[861] It is generally well recognised that Māori health is at a crisis point. The Report notes the significantly higher rates in Māori than non-Māori of: heart disease, strokes, lung cancer, diabetes, asthma, infant mortality, meningococcal disease, schizophrenia, suicide, motor vehicle accident deaths, interpersonal violence, obesity and many other illnesses; at 221-222.
[862] At 226-228.
[863] At 228.
[864] At 228.

made through freeing critical health services and increases in productivity, and this recommendation recognises the need for such data to both justify investment in rongoā, as well as determine appropriate levels for such expenditure.[865]

While it is difficult to ascertain a shift in perspective by a government agency like the MoH towards a system of care like rongoā, the lack of any novel progress since the Report would tend to indicate that little attention has been paid to this recommendation. Progress on updating and supporting rongoā services has been ongoing, however when this is viewed in light of the fact that these have been underway well prior to the Report, it is unlikely that any of the recommendations around this matter have been effected. In 2006, the MoH released a development plan to "…provide a framework for strengthening the provision of quality rongoā services throughout Aotearoa."[866] Following this, a national body for the provision of rongoā – Te Paepae Matua was launched in 2008,[867] and in 2011, Te Kāhui Rongoā trust for the 'protection, nurture and promotion' of rongoā was created.[868] In 2014, new standards were released for the first time in 15 years governing the provision of rongoā.[869] None of these developments appear to have been effected by Wai 262, and in 2011 *Ko Aotearoa Tēnei* was critical of these efforts, noting:[870]

> …there is no sense of abiding energy or purpose about the Crown's actions. Its support for rongoā has been consistently punctuated by delays… It cannot exert any influence over the [district health boards] to contract more services. In 2004, it even took the regressive step of curtailing the funding of rākau rongoā. In the meantime, of course, Maori health problems have festered. The Ministry of Health seems to have lacked the imagination or conviction to engineer a genuine breakthrough or the ability to see the contradiction in its priorities.

Finally, there is no evidence for increased empirical research into the provision or use of rongoā Māori. While there appears to have been preliminary research carried in the wake of the development plan, this too appears to have faltered, and there appears to be no substantive progress on this recommendation.

8.3.4 Other recommendations

One of the other major recommendations of the Report was for the establishment of a Māori advisory committee to provide binding advice to the Commissioner of Patents[871] in a similar manner to the pre-

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[865] At 225-226.
[866] Ministry of Health *Taonga Tuku Iho - Treasures of our Heritage: Ronogā Development Plan* (Ministry of Health, Wellington, June 2006), at 1.
[867] Mita Ririnui "Te Paepae Matua mo te Rongoa, Rongoa National Body launced today" (press release, 16 June 2008).
[868] Ministry of Health, above n 21.
[869] Tariana Turia "New national tikanga standards for rongoā released" (press release, 23 May 2014).
[870] Waitangi Tribunal, above n 847, at 225.
[871] At 91.

existing 'Māori Trade Mark Advisory Committee' established under the Trade Marks Act 2002.[872] While the Patents Act 2013 does implement a Māori advisory committee akin to the trade marks committee, it has considerably more limited scope than recommended in the Report, and does not appear to be a product of the Wai 262 Report.[873] Nevertheless, in principle, the operation of a Māori advisory committee provides a valuable check on decisions where they involve taonga, highlighting the possibility of using the same, or a similar system for CAM products, to protect rongoā and avoid its exploitation or unwanted commercialisation, thus upholding the principles of the Treaty.

8.4 Conclusion

Given the constitutional importance of the Treaty of Waitangi in NZ, as well as the unique opportunity to acknowledge and support rongoā as NZ's traditional medicine, it is surprising that the NHSPB has broadly ignored both of these. This is perhaps best exemplified in the MoH's creation of the Te Kāhui Rongoā Trust for the protection and development of rongoā in 2011, only for this Trust to be avoided in the consultation process for the NHSPB, and for no public regard for their subsequent submission on the Bill in 2015.[874]

In its brief outline of the Treaty and the Wai 262 Report as it affects rongoā, this Chapter sought to acknowledge the fundamental importance of these issues in the development of a novel regulatory scheme for the regulation of CAM products. Consequently, three elements are carried through to the ultimate proposal of this thesis in Chapter 12; protection for rongoā, support for rongoā, and the promotion of a collaborative approach which regulates CAM products, while maintaining a constant, peripheral awareness of the Treaty.

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[872] Trade Marks Act 2002, s177.

[873] Patents Act 2013, at ss225-228; Sullivan and Tuffery-Huria, above n 845, at 409; "…these amendments [to the Patents Act] were proposed before the tribunal's report, and were purposely delayed to provide the government with an opportunity to incorporate any additional points raised by the tribunal."

[874] Te Kāhui Rongoā "Natural Health Products Bill: National Briefing Paper to Minister of Health" (27 August 2015) <http://www.rongoamaori.org.nz>.

Part III: Addressing the Information Deficit & Resultant Problems

9 Public Perceptions on Dietary Supplements: A Pilot Study

> *Science begins with counting. To understand a phenomenon, a scientist must first describe it; to describe it objectively, [she or] he must first measure it.*[875]

9.1 Introduction

The regulatory impact statement for the NHSPB readily acknowledges that there is little information within the government on the scale and nature of the CAM product industry in NZ. There is also minimal recent statistical information on the prevalence of use of CAM products in NZ, or a comprehensive picture of the extent of potentially illegal practices within the industry. The only indications of such practices within the regulatory impact statement show a significant issue, with "…78 percent of the 263 company websites reviewed [being] non-compliant with the Medicines Act…"[876]

Needless to say, it seems somewhat counter-intuitive to introduce a Bill to uncover the extent of an industry and the associated problems, rather than to invest the resources to address the information deficit and legislate in response to identified issues.

This Chapter will first consider the currently available information on usage and marketing of CAM products in NZ, and then discuss and reflect on original empirical work carried out in the course of this research. It will suggest that the prevalence of CAM is much greater than previously thought, and that elements of the packaging and labelling are artfully used to either mislead consumers, or at least confuse them as to the identity and efficacy of CAM products.

9.1.1 Background

From a scientific or statistical perspective, there has been a fair amount of research on international usage of CAM products or modalities.[877] This research indicates a prevalence from 9.8% to 76% of the

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[875] Siddhartha Mukherjee *The Emperor of All Maladies: A Biography of Cancer* (Simon & Schuster, New York, 2010), at 19.

[876] Ministry of Health, above n 3, at 5. A review of CAM product websites was conducted in March 2007 which yielded this data. This non-compliance is largely due to CAM products displaying therapeutic claims. At 6; "In a subsequent compliance awareness programme, the websites reviewed contained advertisements for over 12,000 products with just over half of these advertisements including therapeutic claims. Out of 355 websites reviewed as part of this programme, 107 were found to be making high-level claims."

[877] P. Harris and R. Rees "The prevalence of complementary and alternative medicine use among the general population: a systematic review of the literature" (2000)(8) Complementary Therapies in Medicine 88, and Edzard Ernst "Prevalence of use of complementary/alternative medicine: a systematic review" (2000) 78(2)

public using CAM products depending on the country,[878] and trends of similar or slightly increasing uptake of CAM products where data exists from periodic surveys.[879] However, despite systematic reviews of this data,[880] they bear little direct relevance to NZ given a dearth of comparable usage data and varying demographics used in those studies.[881]

The research conducted in NZ around CAM products is limited. There are two sources of reputable data worth considering; a peer reviewed article on DS prevalence in NZ, and representative research conducted by UMR Research – a market research company.

The only NZ article on prevalence of DS use collates material from two national studies which used personal interviews to collect information;[882] the 1997 National Nutrition Survey, and the 2002 Children's Nutrition Survey.[883] The 1997 survey is most important here, as it is the only data which provides a benchmark for the current prevalence research, however, the 1997 survey considered all 'adults' aged 15 years and older, which makes it difficult to directly compare those results with the present research. In that survey, participants were questioned on DS consumption in the last 24-hours

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Bulletin of the World Health Organization 252; these two systematic reviews summarise the majority of the prevalence studies prior to 2000. Since then notable research includes an Australian study in 2005, Charlie Xue and others "Complementary and Alternative Medicine Use in Australia: A national population-based survey" (2007) 13(6) Journal of Alternative and Complementary Medicine 643, and an update to the earlier paper by Harris et al. in 2012; P. Harris and others "Prevalence of complementary and alternative medicine (CAM) use by the general population: a systematic review and update" (2012) 66(10) International Journal of Clinical Practice 924.

[878] Harris and others, above n 877, at 930.

[879] At 930.

[880] Harris and others, above n 877; Ernst, above n 877.

[881] In the meta-analysis in Harris and Rees, above n 877, there are a wide variety of studies used with age ranges from all ages, to ≥15, 15-64, ≥18, or 45-75. There is more control on age ranges in the second systematic analysis by Harris et al, Harris and others, above n 877, with the majority being 18 or older. More problematic is the definition of 'CAM' and its scope in these surveys. Most studies considered in Ernst, above n 877, and Harris and others, above n 877, specify anywhere between one and 36 CAM products or therapies considered in the study. Consequently, it is difficult to contrast these with the NZ study which has focused solely on dietary supplements in children aged 5-14 and adults aged 15+, Winsome R. Parnell, Noela C. Wilson and Claire Smith "Dietary supplements: Prevalence of use in the New Zealand population" (2006)(63) Nutrition & Dietetics 199, or the current study, which considers adults aged 18+ and refrains from a limited list of CAM products, instead opting for the all-encompassing terms 'dietary supplement' or 'complementary and alternative medicine products'.

[882] Parnell, Wilson and Smith, above n 881; this study involved secondary analysis of two earlier surveys; the 1997 National Nutrition Survey which was a "voluntary cross-sectional survey of New Zealanders aged 15 years and above" (at 200) and contained 4636 participants, while the 2002 Children's Nutrition Survey was the same style survey, but instead, of children aged 5-14 years with 3275 participants. The 1997 survey data quoted herein was performed at a 95% confidence interval with a P-value <0.0001.

[883] At 200.

and the last year.[884] The results from the survey showed 59% of adults (from a sample of 4626 people) had consumed at least one DS in the previous year.[885]

In 2011, UMR Research conducted a representative study of 1000 NZers entitled 'What do New Zealanders believe?'[886] Two questions touched on CAM, with both asking participants to rank how strongly they believed in a statement on an eight point scale from 'absolutely certain it's true' to 'absolutely certain it's not true'.[887] The first statement was 'That arnica reduces bruising', which 72% of people believed,[888] correlating to the top four categories on the eight-point scale; "absolutely certain it's true", "fairly certain it's true", "believe it but not too certain", and "believe it but not at all certain". The second statement was that 'homeopathic remedies are scientifically proven to work', with 51% believing this statement, correlating with the same four categories as for the first statement.[889] Their second study in 2015 looked at NZ science beliefs,[890] asking people to rank statements on a five point scale;[891] with 52% of people agreeing vitamin supplements are a proven way of making people healthier,[892] and 51% agreeing that natural, alternative, holistic health care therapies should have an equal place with conventional western medicine.[893] Agreement in this study

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[884] At 200; In that survey, 'dietary supplements were defined as including "vitamin and mineral supplements … and non-vitamin and mineral supplements, including herbal supplements, sports preparations and garlic powders."

[885] At 200.

[886] UMR Research *Part 2: December 2011 (alternative remedies)* (December 2011); this survey was Part 2 of a multi-part series considering New Zealanders beliefs. This part exclusively considered alternative remedies while Part 1 looked at New Zealanders' religious beliefs and their beliefs in paranormal events, and future parts were set to look at beliefs around Māori culture and climate change.

[887] At 5-6.

[888] At 5; Arnica is almost exclusively used as a homeopathic preparation derived from the flowers of the herbaceous plant *Arnica montana*. While in theory an undiluted form of the plant could be used, this is very rare, in part due to its toxicity from the presence of Helenalin which causes skin irritation and can cause gastrointestinal discomfort and bleeding if taken internally. Consequently, the form of Arnica widely available in pharmacies, health stores and online is the homeopathic variety, which double-blind, placebo-controlled, randomised clinical studies and systematic reviews have demonstrated to be no more effective than a placebo; C. Stevinson and others "Homeopathic arnica for prevention of pain and bruising: randomized placebo-controlled trial in hand surgery" (2003) 96 Journal of the Royal Society of Medicine 60, E. Ernst and MH. Pittler "Efficacy of Homeopathic Arnica: A Systematic Review of Placebo-Controlled Clinical Trials" (1998) 133(11) Archives of Surgery 1187.

[889] At 6.

[890] UMR Research *Science Beliefs* (September 2015); this study was part of a broader 'New Zealand Insight' study, of which one part focused on New Zealanders' science beliefs. The questions in this part were generally broad, ranging from climate change, immunisation, fluoride in water, evolution and more.

[891] The five points on the scale were; 'strongly agree', 'somewhat agree', 'unsure', 'somewhat disagree' and 'strongly disagree'.

[892] At 'Alternative Health'.

[893] At 'Alternative Health'; these answers are the UMR totals from the two 'agree' points on the five point scale outlined at footnote 891.

included “strongly agree”, and “somewhat agree”, while those who were “unsure” were not included in the total ‘agreeing’ or ‘disagreeing’ with the statements.

9.1.2 The purpose of the pilot study

This research attempts to collect empirical information to provide a foundation for the design of legislation which takes account of current and potential problems. Any effort to attain the necessary data to uncover the problems in need of attention would require a multi-disciplinary sciento-legal approach which considers matters ranging from usage, efficacy, and safety through to the marketing of CAM products and whether they directly or implicitly exhibit misleading or deceptive conduct with respect to their efficacy, safety or other matters. As such, this study begins the process of gathering data on the prevalence of use of CAM products, as well as conducting a survey to assess the effect of TCs, DS labels, packaging, environment of sale and other matters associated with CAM products, as well as ascertaining which factors are most influential upon consumers.

There is little information on the legal effect of the marketing of CAM products or factors affecting consumer perceptions and decision making. As noted at 7.3.2, there is a history of FTA surveys, which have generally been used to aid in determining whether conduct is misleading or deceptive.[894] More specifically, the survey in *Aneheuser-Busch v Budweiser Budvar*[895] showed participants product images for 30-seconds, followed by a series of questions on the products they had just seen in order to assess consumer perceptions; a strategy of substantial value in collecting generalised data on consumer perceptions.[896]

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[894] See *Levi Strauss & Co v Kimbyr Investments Ltd*, above n 663, *Commerce Commission v Griffins Foods Ltd* [1997] DCR 797 (DC), and *Cookie Time Ltd v Griffins Foods Ltd*, above n 664.

[895] *Anheuser-Busch Inc v Budweiser Budvar National Corp*, above n 664.

[896] In the survey referred to in this case, 511 participants were shown three bottles of beer for 30 seconds, one being Budvar. The survey questions went on, in a somewhat leading fashion, if they had recalled something similar to ‘Budweiser’ to ask whether the expected an association with Budweiser due to the name. In this case, Doogue J had two problems with the survey. Firstly, he saw that the questioning was leading, and secondly, that “the survey was as far removed from a practical purchasing situation as the presence of a number of bottles before me in the courtroom.” This second issue was largely due to participants being shown a single bottle, rather than the 4-pack or 6-pack that Budvar or Budweiser respectively were packaged with in a supermarket. These problems are not endemic to this kind of study (a limited-time exposure study), but rather were foibles of the *Budweiser* case, and as such, the value of this type of study in the presence instance is not diminished. As an aside, the survey in *Budweiser* was still admissible, however its probative value was somewhat lessened due to the quality of the survey – an assessment the court makes on the evidence. Trotman and Wilson, above n 641, at 148-150.

9.2 The Pilot Study: Methods

9.2.1 Sample & study design

This study consisted of an empirical legal questionnaire of NZ university students[897] on their perceptions of CAM products, alongside those of food and medicines.[898] The study utilised both qualitative and quantitative questions coupled with time-limited exposure to CAM products on sale in NZ to test the effect of the marketing, and specifically TCs upon consumers.

9.2.2 Data collection[899]

The questionnaire was distributed entirely through the online survey platform Qualtrics.[900] Respondents were provided with the web address for the survey and subsequently anonymously completed the survey online.

The survey went live on 5 September 2016 and remained open for three weeks. Participants were recruited through social media, e-mails and short presentations in lectures at the University of Canterbury. In total, 535 partial or fully completed responses were returned by the end of the survey period, however, when the responses were limited to students, there were 426 useable surveys, with the other 109 comprising non-students or submissions where no questions had been answered. This student demographic was selected as it comprised the largest commonality between respondents, and made the survey slightly more representative of a subset of society.

Given the selection of respondents to those who identified as 'students' when asked about their primary occupation,[901] it is unsurprising that 84% of respondents were aged 18-24, while 10.3% were 25-34 years old. The female to male response rate was slightly skewed at 66.1% to 31.1% respectively, but this may be indicative of both the marketing of the survey, and a gender-linked interest to the subject matter. The ethnicity of respondents followed expected trends, with 69.7% NZ

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[897] While this study was primarily conducted at the University of Canterbury, there was no identification of the tertiary institution with which participants were associated if they selected 'student' as their occupation.

[898] Empirical legal research or empirical legal studies (ELS) is a relatively novel field of legal research which employs both quantitative and qualitative data either instead of, or in association with traditional legal analyses in order to more readily inform decision making and to determine the effects of legal and regulatory undertakings. See Peter Cane and Herbert M. Kritzer (eds) *The Oxford Handbook of Empirical Legal Research* (Oxford University Press, Oxford, 2010) for the authoritative exposition on ELS, and see Marie M. Bismark "Learning from claims and complaints: an epidemiological approach to medical regulation" (Doctor of Medicine collection of works, University of Otago, 2015) for the application of ELS in a medico-legal context.

[899] This study received approval from the University of Canterbury Human Ethics Committee on 5 August 2016 (approval reference HEC 2016/37/LR), see Appendix 1.

[900] Qualtrics "Qualtrics Software" (Computer Software, 2005) online <www.qualtrics.com>, used under licence to the University of Canterbury.

[901] Question 4, Survey 1.

European/Pākehā, 12.2% Asian, and 4.5% Māori respondents. Both education history and income aligned with the student demographic, with the majority having a high-school education (69.1%), and earning less than $10,000 annually (68.6%).

9.2.3 Questionnaire design[902]

In designing the questionnaire, several factors were brought together from other cases, surveys and reports on the best strategy for conducting a study of this nature.[903] Given the multidisciplinary nature of the subject area, international studies on similar issues come from a variety of backgrounds, ranging from epidemiological and public health backgrounds, through to private research companies conducting such studies under contract to governments. The element of difference here is the focus on a sciento-legal study which endeavours to amalgamate sound empirical data collection with an FTA style study, which tests marketing or sub-conscious influences on the reasonable consumer.

In order to combine these disparate elements, parts of the study were purely quantitative, in order to assess CAM or evidenced-based medicine usage in the style of international studies on these questions. In contrast, other parts merged quantitative and qualitative questions in the FTA-style test,[904] where three of six products were randomly shown to a participant for 30 seconds, followed by a series of questions. This sought to determine the factors which influence consumer decision making, with a focus on four key elements: TCs, packaging, DS label, and name recognition.

The remainder of the questionnaire employed a mix of questions to either expand upon, or provide a check to previous questions. This also allowed inclusion of further questions on tangential issues like the environment of sale, and people's behavioural responses to minor illness, or a desire for better health; all issues where the results indicate scope for further study.

9.2.4 Data analysis

The responses from 109 participants who did not identify as 'students' were discarded. Both completed and partially-completed questionnaires were utilised, insofar as the questions they answered.

Analysis of the data and statistical parameters[905] was aided by consultation with health-sciences statistician, Pat Coope. The majority of the data was analysed using Qualtrics, although qualitative

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[902] See full survey at Appendix 2.
[903] See material previously discussed on Empirical Legal Research at fn 898, the FTA style survey in *Anheuser-Busch Inc v Budweiser Budvar National Corp*, above n 664, as discussed at fn 896, and the three systematic reviews of CAM prevalence studies at fn 877.
[904] See 9.2.1.
[905] See 9.2.5.

data were processed using NVivo 11.[906] There was no weighting applied to the reported data as precise demographic information for the student cohort was difficult to obtain, and it is recognised that the data were also not representative of the student population.[907]

9.2.5 Statistics

A normal distribution is used throughout the analysis to determine the probability of a particular response in the general population, and importantly to calculate the margin of error on the reported results.

As such, the margin of error is reported on the data as presented throughout the results,[908] based on a normal distribution at a 95% confidence level. The overall standard error of the survey is ±4.75%. Unless otherwise noted, all the figures in these results have been rounded to one decimal place.

9.2.6 Study limitations

Despite the lack of representativeness, the data merely provides a snapshot of a subset of society and their behaviour with respect to CAM products, which is further built upon in the second questionnaire study in Chapter 10.

There were also a couple of other issues which arose throughout the survey, which may have resulted in lower accuracy than initially desired. These issues include the overall length of the survey, occasional confusion regarding the expectations of questions or implied definitions, and one particular logical inconsistency.

These issues were minor, and few anomalies were evident from their presence, except for a higher than anticipated level of atrophy due to the survey length. Consequently, only one issue was expressly corrected for.[909]

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[906] QSR International "NVivo 11 Qualitative Data Analysis" (Computer Software, 2015) online, used under licence to the University of Canterbury.

[907] There were a number of indicators that the data were not representative. John Gerritsen "Female enrolments fall at Canterbury University" *Radio New Zealand* (New Zealand, 18 August 2016) demonstrated that female enrolments comprised 49.6% FTE students at the University of Canterbury in 2015; a proportion not reflected in the Pilot Study. An additional complicating matter was somewhat targeted recruitment, which favoured students who were likely to take an interest in the research being conducted. Recruitment was directed most heavily towards Law subjects, followed by Psychology, and Chemistry/Biochemistry, which in contrast to typical STEM subjects, generally show a higher proportion of women.

[908] See 9.3.

[909] Questions 26 and 29 were removed from analysis due to a logical inconsistency. These two questions implicitly expected participants to put themselves in the shoes of someone looking to purchase the product they had just viewed. This presumption was not immediately apparent to participants, yielding answers which offered little to no value to the survey overall, and thus will be excluded from further analysis.

9.3 Results & Discussion

The results in the following section are presented alongside the discussion on their implications. There are three parts to this section; the first on general perceptions and the usage of medicines and CAM products, followed by the analysis of the six products and people's perceptions around them, and finally, a brief consideration of the impact of the environment of sale.

9.3.1 General perceptions and prevalence

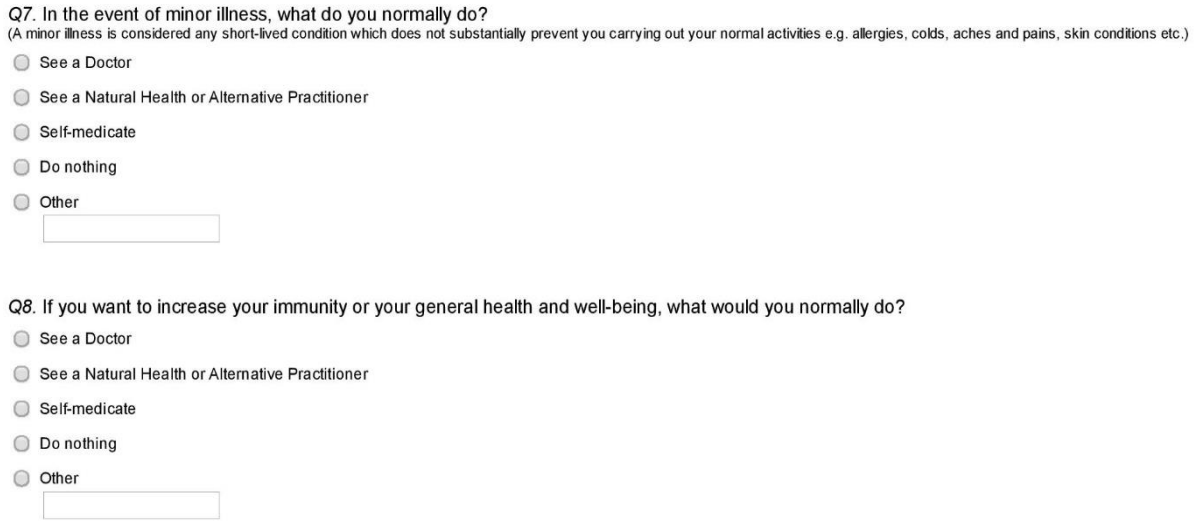

Figure 9.1: Survey 1 - Questions 7 & 8

	Minor Illness (%) Question 7	Increase Immunity (%) Question 8
Self-medicate	51.9±4.8	46.4±4.8
Do nothing	28.9±4.4	17.3±3.6
See a doctor	16.4±3.6	17.8±3.7
Something else/other	1.9±1.3	11.8±3.1
See a natural health practitioner	1.0±0.9	6.3±2.4

Table 9.1: Survey 1 - Results to Questions 7 & 8 - Responses to minor illness or desire to increase general immunity

When participants were questioned on their practical response to a minor illness or a desire to increase immunity at questions 7 and 8, their answers showed a similar approach to both matters, as seen in Table 9.1. However, when seeking to increase immunity, respondents were more likely to take another action entirely, as evidenced by a heightened selection of 'Something else/other', with common responses including changing eating or exercise habits.

Q9. How often do you take non-prescribed medicines?

- ○ Daily
- ○ Weekly
- ○ 2-3 times per month
- ○ 1-2 times per month
- ○ 1-2 times per 6 months
- ○ 1-2 times per year
- ○ Less Frequently
- ○ Never

Q10. How often do you take dietary supplements or natural health products?

- ○ Daily
- ○ Weekly
- ○ 2-3 times per month
- ○ 1-2 times per month
- ○ 1-2 times per 6 months
- ○ 1-2 times per year
- ○ Less Frequently
- ○ Never

Figure 9.2: Survey 1 - Questions 9 & 10

	Non-Prescribed Medicines (%) Question 9	CAM Products (%) Question 10
Daily	6.3±2.3	26.3±4.2
Weekly	13.0±3.2	14.5±3.4
2-3 times per month	12.7±3.2	8.0±2.6
1-2 times per month	16.1±3.5	5.1±2.1
1-2 times per 6 months	14.7±3.4	5.8±2.3
1-2 times per year	11.3±3.0	6.3±2.3
Less frequently	12.0±3.1	10.6±3.0
Never	13.9±3.3	23.6±4.1

Table 9.2: Survey 1 - Results to Questions 9 & 10 - Responses on frequency of consumption of non-prescribed medicines and CAM products

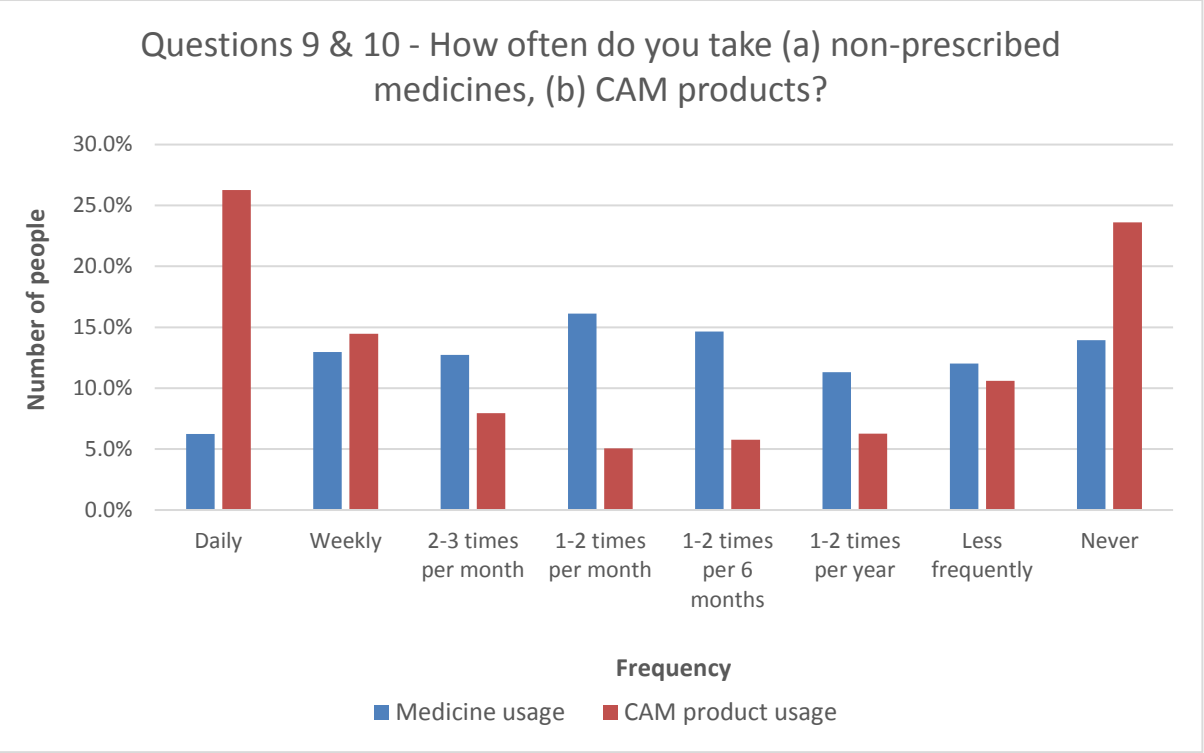

Figure 9.3: Survey 1 - Results from Questions 9 & 10

Questions 9 and 10 studied how frequently respondents consumed either medicines or CAM products, with the ensuing results in Table 9.2 being one of the primary reasons for conducting this research. There was no comprehensive data on NZers usage of CAM products, and while the information below only informs about usage in the surveyed student demograph, it provides an enlightening illustration of how a generally low-income,[910] well-educated[911] sector of society use general sale medicines and CAM products.

The general trends in Figure 9.3 show that while a greater number of people have consumed non-prescribed medicines in the past (86.1±3.3%) than CAM products (76.4±4.1%), the frequency at which people consume CAM products is significantly higher than that for medicines. This would tend to support the hypothesis that people take CAM products more readily for prophylaxis, whereas medicines tend to be consumed as a treatment in the event of illness.

[910] 68.5% of respondents earned less than $10,000, while 18.7% earned $10,000-$19,999.
[911] 69.1% of respondents listed 'High School' as their highest level of education, with 15.6% holding an undergraduate tertiary qualification.

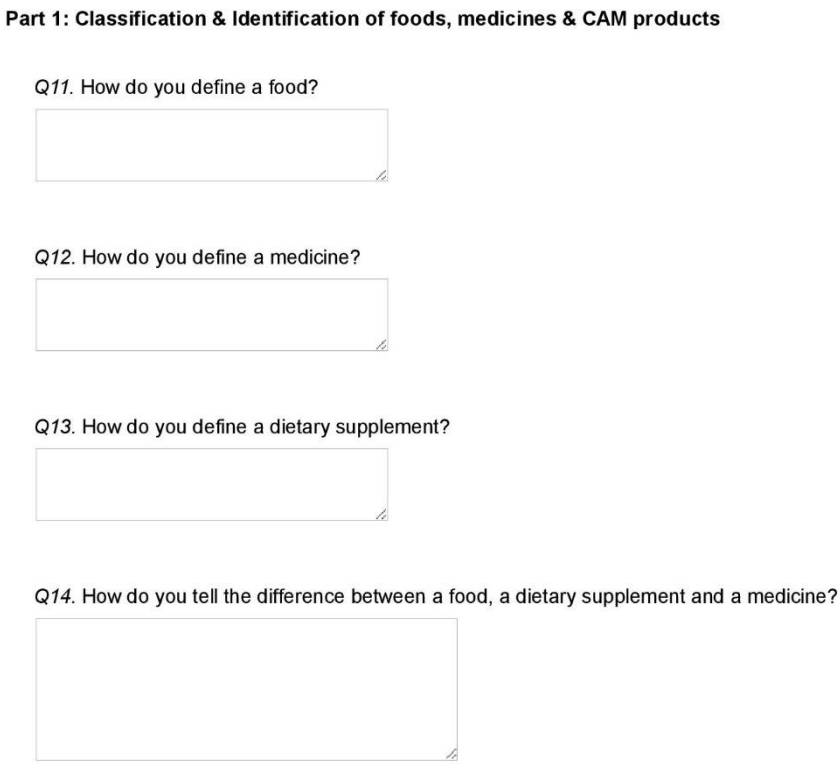

Figure 9.4: Survey 1 - Questions 11-14

Questions 11-14 turned from quantitative to qualitative, and asked participants to define food, medicines and DSs, and then how they distinguished between the three. The responses to these questions only offer basic themes as depicted in the word clouds (Figure 9.5-Figure 9.8), but nevertheless provide an insight into respondents' views of these products. It is important to note that while the larger words appear to dominate the word-clouds, they only account for a maximum of approximately 9% weighted frequency.

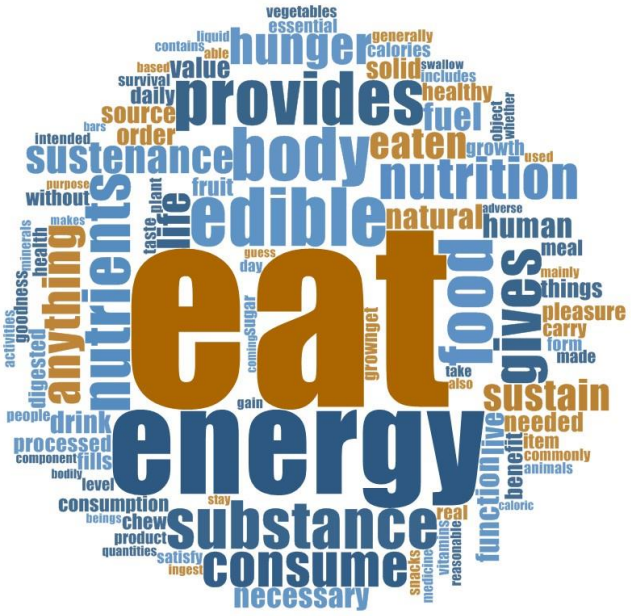

Figure 9.5: Word cloud for Question 11 - definition of food

Unsurprisingly, food was generally viewed as 'something which you eat that gives you energy'. When people delved deeper into this definition, the purpose of eating or justifications for doing so became important, with prominent terms like 'energy', 'nutrients', 'sustenance' and 'hunger'.

Figure 9.6: Word cloud for Question 12 - definition of medicine

A similar approach was taken for medicine, with people divided into two groups; either those that defined it for its curative properties in treating illness, or those who saw it as a means to return to normality or improved health. This was exemplified in the heightened frequency of words like 'illness', 'help', 'better', 'cure' and 'health'.

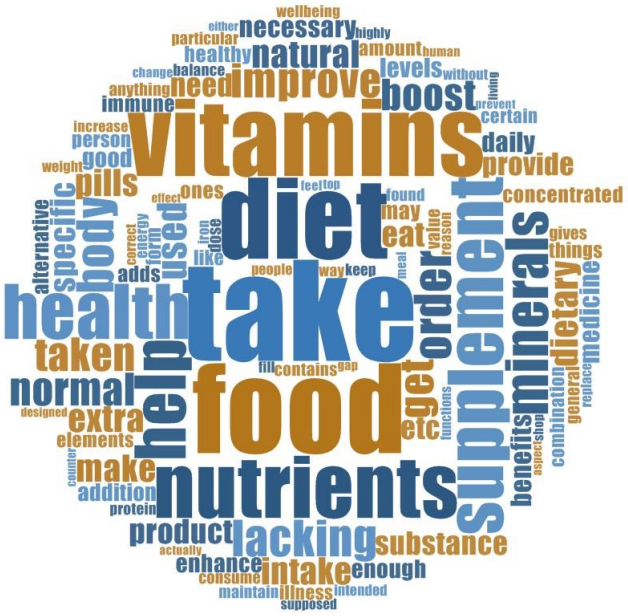

Figure 9.7: Word cloud for Question 13 - definition of dietary supplement

In defining DSs, there was much less cohesion between answers; however, the common theme which arose was an inclination to disambiguate 'dietary supplements' by separating the words into its morphemes and defining it as such: for example 'things which supplement your diet'. A number of people also took the opportunity to define DSs by some of the products under this umbrella, like 'vitamins' and 'minerals', with a surprising prominence of 'food' in this word cloud too.

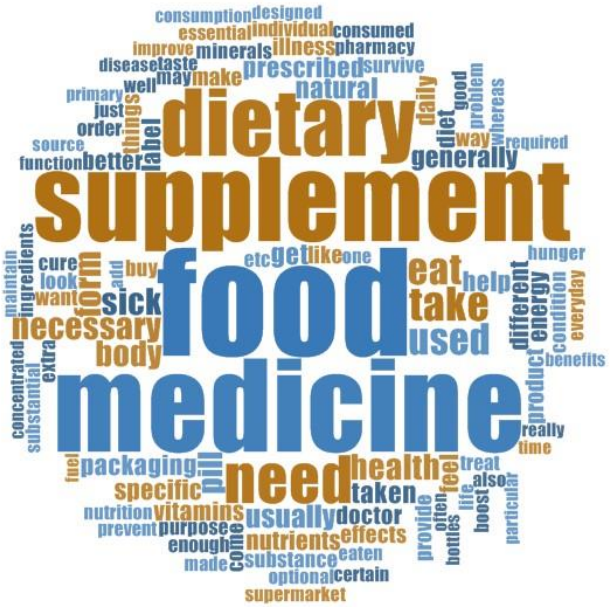

Figure 9.8: Word cloud for Question 14 - differences between food, medicine and dietary supplements

When considering the differences between the previous three categories in question 14, the word cloud becomes less informative. However, a review of the responses to this question shows something of a pattern. While the question asked respondents how they differentiated between these products in practice, responses instead focused on the relative necessity of these products;

namely that food was a necessity for survival, medicines were only needed when a person was sick, and DSs were either unnecessary or a means of correcting a deficiency.

Questions 15-17 took a different approach to same question, with much more informative results.

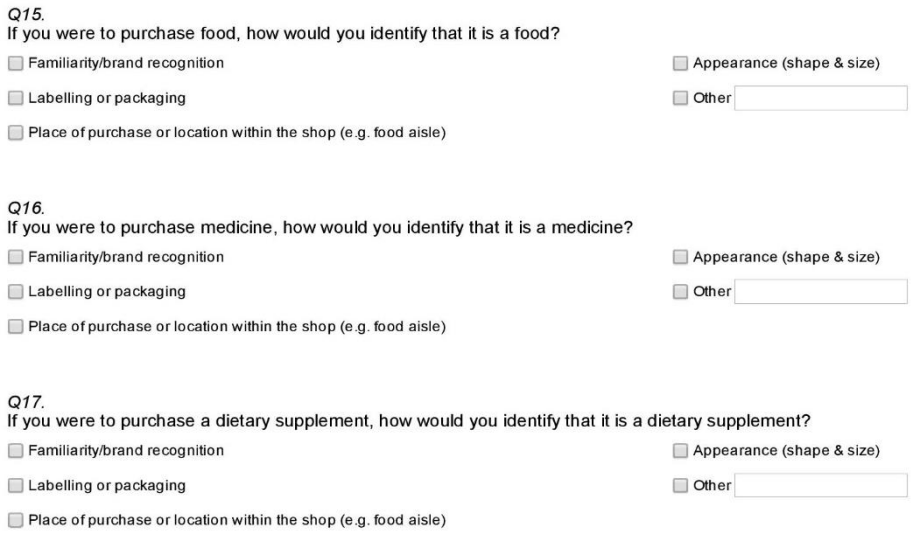

Figure 9.9: Survey 1 - Questions 15-17

	Food (%) Question 15	Medicine (%) Question 16	Dietary Supplement (%) Question 17
Labelling or Packaging	65.4±5.0	83.4±3.9	89.5±3.2
Place of purchase or location within shop	49.1±5.3	50.9±5.3	42.4±5.2
Familiarity/brand recognition	57.3±5.2	43.3±5.2	36.1±5.1
Appearance	59.6±5.2	28.2±4.8	20.4±4.3
Other	8.1±2.9	9.0±3.0	4.7±2.2

Table 9.3: Survey 1 - Results to Questions 15-17 - Factors used in identification of food, medicines and dietary supplements

Questions 15-17 were a quantitative corollary to questions 11-14; asking participants to select up to five factors which they used in identifying food, medicines or DSs. The trends in their responses can be immediately seen in Table 9.3, with the four main factors being comparable in the case of food, but increasingly distinct for medicine and DS identification. This suggests that the labelling and packaging become increasingly important as consumers become less certain of the identity of the product. When the goods cannot be immediately recognised as a food from their appearance or a familiarity with the goods, then consumers look instead at how it is packaged, and what is displayed on the packaging to identify the goods, and in all likelihood the effect of medicine or DS.

9.3.2 Products

As mentioned earlier, identifying people's perceptions in relation to six products was one of the primary goals of this study.[912] This section focuses on the results from those questions and a preliminary discussion, before delving more deeply into a theory on the public's classification of CAM and medicinal products based upon these results at 9.3.3.

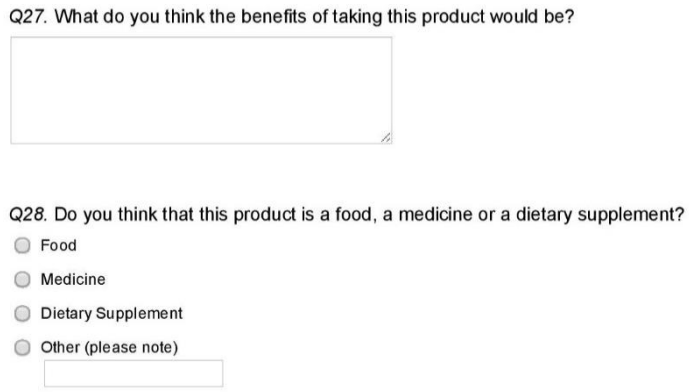

Figure 9.10: Survey 1 - Questions 27 & 28

Figure 9.11: Survey 1 - Question 30

Three questions warrant discussion here; questions 27, 28 and 30.[913] Question 27 takes a qualitative approach, asking participants what they think the benefits of taking the product will be, while questions 28 and 30 are quantitative, and ask respondents to identify the product and rate how effective it will be at therapeutic purposes respectively.

Six products were shown to participants; Probiotics IBS Support, Advil, Olive Leaf, Arnica, Folic Acid, and Ultivite. Probiotics IBS Support is a listed therapeutic good in Australia and likely a DS in NZ despite not being correctly labelled. It allegedly comprises billions of 'good' bacteria, and claims to offer relief from the symptoms of Irritable Bowel Syndrome.[914] Advil is an NSAID containing ibuprofen and thus

[912] See 9.2.1 and 9.2.3.
[913] See 9.2.6 on why questions 26 and 29 will not be discussed.
[914] See Figure 9.12: Probiotics IBS Support.

Figure 9.12: Probiotics IBS Support

Figure 9.13: Advil

Figure 9.14: Olive Leaf 3500

Figure 9.15: Arnica 6x Drops

Figure 9.16: Folic Acid

Figure 9.17: Men's Ultivite

a medicine, and is included as a control to the CAM products.[915] Olive leaf is a herbal remedy, and thus a DS, which claims to be effective a relieving cold symptoms and fighting common viral infections.[916] Arnica is a homeopathic remedy which offers speedy recovery from sports or injury, and while strictly a food, could reasonably be considered a DS under current regulations.[917] Folic Acid is also known as vitamin B9, and while a DS, it has positive effects at reducing likelihood of birth defects like spina bifida when taken during pregnancy.[918] Finally, Ultivite is a multivitamin aimed at men, which falls squarely within the realm of DS, and is intended to supplement mineral, vitamin, and antioxidant consumption, or correct deficiencies.[919]

Qualitative analysis of the results from question 27 shows one particular trend. When questioned on the benefits of the product, people consistently used the words on the label or derivatives. While the frequency of these words varies significantly from Advil's 'pain' at 26.6%, to Ultivite's most popular word 'vitamins' at 7.8%, a similar pattern is seen across all six products. Probiotics and Advil have eight of the top ten words on the label,[920] Folic Acid has six of ten,[921] and Olive Leaf has five of ten,[922] while Arnica and Ultivite show four words on their labels from the top ten used by respondents in answering question 27.[923]

Question 28 asked participants whether the product they had just viewed was a food, medicine or DS. As can be seen from the histogram in Figure 9.18, people identified the majority of these products correctly. Nevertheless, Probiotics, Olive Leaf, and Arnica all display unexpected results; however, some background is required to appreciate the potential anomaly.

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[915] See Figure 9.13: Advil.
[916] See Figure 9.14: Olive Leaf 3500.
[917] See Figure 9.15: Arnica 6x Drops.
[918] See Figure 9.16: Folic Acid.
[919] See Figure 9.17: Men's Ultivite.
[920] Probiotics IBS Support (in descending order of frequency): 'bowel', 'irritable', 'syndrome', 'IBS', 'symptoms', 'relief', 'good' and 'bacteria'. Advil (in descending order of frequency): 'pain', 'headaches', 'relieves', 'fast', 'muscle', 'period', 'back', and 'aches'.
[921] Folic Acid (in descending order of frequency): 'brain', 'development', 'nerve', 'healthy', 'acid', and 'folic'.
[922] Olive Leaf (in descending order of frequency): 'cold', 'symptoms', 'help', 'relieve', and 'fight'.
[923] Arnica (in descending order of frequency): 'injury', 'sports', 'recovery', and 'speedy'. Ultivite (in descending order of frequency): 'vitamins', 'health', 'minerals', and 'men'.

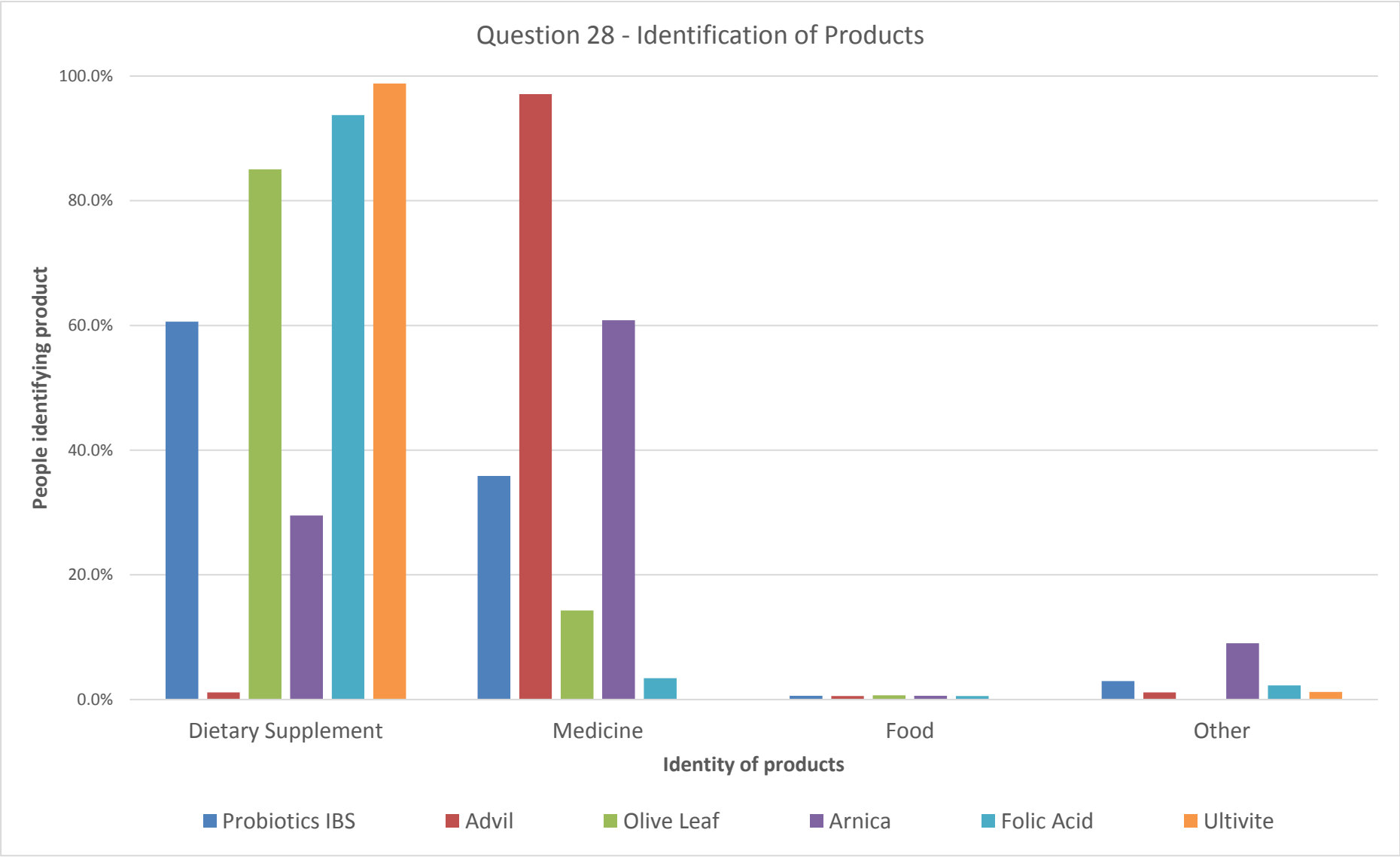

Figure 9.18: Survey 1 - Question 28 - Respondents' identification of six products

One of the hypotheses which this study sought to test was that TCs, which are required for medicines but prohibited for DSs, would consequently cause people to be more inclined to view a product with a TC as a medicine. Given the TC on Olive Leaf, it was expected that there would at least be some uncertainty, if not an outright classification of the product as a medicine due to this claim. However, Figure 9.18 clearly shows this is not the case, with the more questionable claims on Probiotics IBS and Arnica having a greater effect upon participants' identification of these products, compared with Olive Leaf's unambiguous identification as a DS.[924] The results for Arnica illustrate this particularly well, with 60.8±7.4% incorrectly identifying it as a medicine, instead of a DS. While it is probable that Arnica does display a weak TC, this demonstrates that TCs are certainly not the only factor which is influencing consumer decision making and identification of these products, but rather is likely one of a number of factors, as discussed further at 9.3.3.

Question 30 was also quantitative, but asked people how effective they thought the products would be in achieving one of the four therapeutic purposes posited by reg11 DSRs. Participants were asked to select an option for each of the four purposes from a scale of; extremely effective, very effective, moderately effective, slightly effective or not effective at all. The results of one of the four 'effective' categories are displayed in Figure 9.19, with the remainder comprising the 'not effective at all' category. The purpose of this question was generally to assess the impact of TCs on consumers, but more specifically, to see whether people noticed the claims, and in the event they did, whether this led to them believing that the product would be more effective than if it did not display such a claim.

[924] See the detailed discussion on the therapeutic claims at Table 9.4: Therapeutic Claims and Misleading Statements.

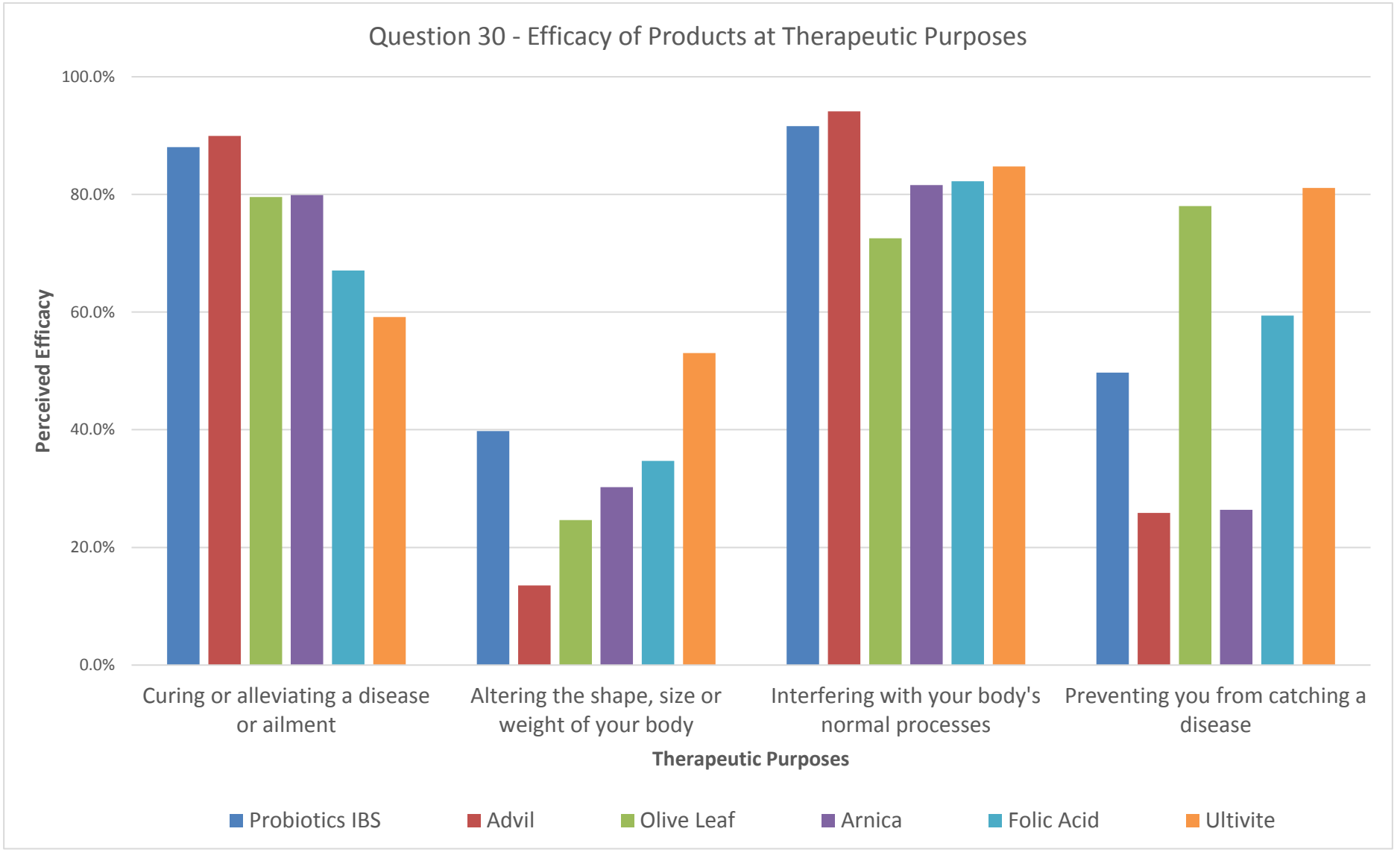

Figure 9.19: Survey 1 - Question 30 - Respondents' perceptions on efficacy of six products at therapeutic purposes

The results in Figure 9.19 provides an interesting comparative picture, but those of Advil, Olive Leaf and Ultivite best demonstrate the effects of this question. Taking the medicine Advil as the first example, it can be seen that there is a high level of certainty that the product will cure or alleviate a disease or ailment and interfere with the body's normal processes. This correlates with the TC on Advil which begins "relieves pain fast…" Advil is seen to be ineffective at the other two purposes, as indicated by the substantially lower perceived efficacy. In a similar vein, Olive Leaf shows a relatively high level of perceived efficacy in all categories except for altering the shape of one's body. Again, this tends to align with the broad TC stated on the packet; "Relieves cold symptoms, Helps fight common viral infections". On the basis of these two examples, the results appear to indicate that people are noticing the TCs, and as a result believe the products will be effective at achieving these stated purposes.

However, it is a different picture when the results from Ultivite are considered. There is nothing close to a TC on the Ultivite packaging, but merely a description of the constituents of the multivitamin and the target audience. Nonetheless, participants have responded to question 30 that Ultivite will be at least somewhat effective at all four of the therapeutic purposes. This immediately dispels the theory that people are convinced about the efficacy of a CAM product solely by a TC, but rather poses another rationale, which explains the results seen in Figure 9.19. The trend seen for Advil and Arnica above certainly exists, and people are clearly noticing TCs, however the question remains of how people are responding to them, given the Ultivite results. In light of the similar trends with both Ultivite and Folic Acid in Figure 9.19, it would appear that people are using TCs to pinpoint the product's effect.

Taking this one step further, it would appear that the strength of the TC also plays a role in how certain participants were, about the effect of the product. Generally, Advil showed the greatest margin between the peaks and troughs of its four bars, while Probiotics IBS Support was below average, and Folic Acid and Ultivite displayed the least margin. It can thus be surmised that the stronger the TC, the more certain consumers are about the particular effect of the product.

Despite both question 28 and 30 disproving the hypothesis that a TC displayed on a CAM product either leads to that product more readily being identified as a medicine, or informs consumers about the efficacy of that CAM product, they have nevertheless shown that TCs play some role in consumer decision making, but that role is likely inseparable from a number of other factors rather than standing alone.

9.3.3 A theory on the public's classification of CAM and medicinal products

The hypothesis that the unlawful presence of TCs on CAM products could cause consumers to confuse these products with medicines has been at least partially disproved by the results in 9.3.2. Nevertheless, it is worth considering the TCs on the products used in this survey, and the extent to which the statements on these products are misleading or deceptive, in line with either the DSRs or FTA.

Therapeutic Claims and Misleading Statements

This section momentarily moves away from the results of the survey, to discuss whether the statements on the labels of the six products used in the study are either TCs within the meaning or reg11 DSRs,[925] or are misleading and deceptive statements in the vein of reg10 DSRs[926] and the FTA.[927] Consequently, this analysis of the claims is an exercise in statutory interpretation.

For the most part, the analysis in Table 9.4 is uncomplicated. It is important to bear in mind that while alternative arguments are possible, especially for products like Arnica and Probiotics IBS Support, participants only had 30 seconds to consider the products in an attempt to replicate the shopping environment where people tend to make quick decisions, rather than analysing statements in depth. The analysis in Table 9.4 considers whether the 'nature' of the CAM products was misleading by way of TCs,[928] applying the objective standard of the reasonable person to this statutory interpretation.

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[925] Dietary Supplements Regulations 1985, reg11: "Except as permitted by the Medicines Act 1981 and any regulations made under the Act, no dietary supplement shall be advertised or labelled with a statement relating to any of the following matters:

(a) treating or preventing disease:
(b) diagnosing disease or ascertaining the existence, degree, or extent of a physiological condition:
(c) altering the shape, structure, size, or weight of the human body:
(d) otherwise preventing or interfering with the normal operation of a physiological function, whether permanently or temporarily, and whether by way of terminating or reducing or postponing, or increasing or accelerating the operation of that function, or in any other way."

[926] At reg10: "…(2) No printed, pictorial, or other descriptive matter supplied or displayed with any dietary supplement shall include any false or misleading statement, word, brand, picture, or mark purporting to indicate the nature, suitability, quantity, quality, strength, purity, composition, weight, origin, age, effects, or proportion of the dietary supplement or of any ingredients of the dietary supplement."

[927] See Chapter 7.

[928] Dietary Supplements Regulations 1985, reg10(2).

Product	Statement	Is this statement a therapeutic claim?	Therapeutic Claim Rationale (Regulation 11 DSRs)	Is this statement misleading?	Misleading Statement Rationale (Regulation 10 DSRs & s10 FTA)
Advil	Relieves pain fast •Headache •Back Pain •Muscle Pain •Period Pain	Yes	Not subs(a), (b) or (c), but comes under (d). Pain is a normal 'physiological function' and this TC states that it 'relieves pain', which amounts to a reduction or termination of that function.	Unlikely	This statement does make Advil out to be a medicine, but it is obviously not misleading, as Advil is in fact a medicine, as distinct from the other five products which are DSs.
Arnica	Speedy recovery after sports or injury	Probably	Two possibilities for TC under subs(d). 'Injury' may be a physiological condition, and thus 'speedy recovery' from this would be interference. Alternatively, healing is probably a physiological function, and it is likely that 'speedy recovery' is tantamount to 'increasing or accelerating' healing function.	Unlikely	Quite broad, lacks any identification of specific problem that this will solve. Statement could equally be applied to water for example. Increasing something that is already occurring (recovery) but no certainty as to how it will achieve this. The claim alone is unlikely to mislead people into thinking it is a medicine.
Folic Acid	Supports healthy brain and nerve development	No	Certainly not subs(a), (b) or (c). Question is whether 'support' implies 'interference' within meaning of subs(d). Very unlikely, given broad nature of claim which could similarly apply to any food or beverage.	Unlikely	Breadth of the statement, coupled with the term 'support' implies that the product is generally helping what is already occurring. Akin to many DSs, and quite distinct to medicine labelling.
Olive Leaf	Relieves cold symptoms Helps fight common viral infections	Yes	A cold is a disease, so relief of cold symptoms is treatment of the disease under subs(a). Furthermore, fighting viral infections is certainly an attempt at preventing disease under subs(a). Also see similarity to TC for Advil.	Probably	Names specific medical condition (cold), addresses the root of the problem (symptoms), and tries to prevent succumbing to disease. Shares specificity and direct problem solving ability with Advil label ∴ misleading.
Probiotics IBS Support	For the symptomatic relief of medically diagnosed irritable bowel syndrome	Probably not	Certainly not subs(b) or (c), nor probably (d), as IBS is not physiological function. Questionable whether IBS is a disease for purposes of subs(a). If so, then 'symptomatic relief' will probably amount to treatment or prevention.	Probably	Addresses a medical condition, directly references the medical input (diagnosis), and proposes relief from symptoms. Almost certainly fits within s4 MA definition of therapeutic purpose, and very likely medicine label.
Ultivite	Multivitamin mineral & antioxidant with herbs Formula 1 In Natural Health 40+ Years	No	No attempt at TC. Merely a statement as to the contents, with nothing in regards to effect or mode of action of the product.	Unlikely	Uses terminology commonly associated with DSs. Also nothing medicinal whatsoever in the nature of the statement.

Table 9.4: Therapeutic Claims and Misleading Statements

Having established the presence or absence of TCs and misleading statements on the products tested in this experiment, it is now possible to place them into the bigger picture, and consider how multiple factors are likely at play in effecting consumer decision making with regards to the CAM products which they purchase.

Multiple Factors in Decision Making

Once it became evident that the TCs were by no means the only, nor perhaps even the most important, factor in people's decision making, it became necessary to take a broader approach to the initial thesis, that TCs substantially affect consumer identification of CAM products. Four factors crystallised from the results in section 9.3.2; the 'dietary supplement' label, the packaging, TCs and name recognition. Table 9.5 highlights the presence or absence of these characteristics, grouping this with how the majority of participants identified each of these products at question 28. An explanation and justification for each of the four heads follows.

Product	(Primary) 'Dietary Supplement' Label	(Secondary) Packaging	(Tertiary) Therapeutic Claim	(Quaternary) Name Recognition	Identification
Advil		Box	✓	✓	**Medicine**
Folic Acid	✓	Bottle		✓	**Dietary Supplement**
Olive Leaf	✓	Bottle	✓	?	
Ultivite	✓	Bottle			
Arnica		Box	✓	?	**Probably Med**
Probiotics IBS		Bottle	?	✓	**Probably DS**

Table 9.5: Factors employed in identification of products

Where 'Dietary Supplement', or some iteration thereof,[929] appeared on the labels of these products, they were unequivocally identified by participants as DSs. While this statement is required to appear on the label, not all DS accord with such requirements.[930] Given the effect of a 'dietary supplement' note on the label, this has been categorised as the primary consideration, although it is by no means the only factor, used by participants in identifying the products.

The secondary factor which has been identified from the results is that of the nature of the packaging. From the results, one trend leapt out, which was that people readily associated medicines with boxes, and DSs with jars or bottles. Advil and Arnica were displayed in boxes as the packaging which was presented to the consumer, while the other four products came in plastic bottles or jars. There has

[929] See Folic Acid, which merely stated 'dietary' on the label.
[930] Dietary Supplements Regulations 1985, reg5(1)(e).

been a substantial amount of research around the effect of pharmaceutical pill size and colour,[931] with recent research showing the packaging of medicines as an indicator to consumers, of the product's efficacy or potency;[932] adding credence to the theory that the packaging plays a large role in influencing consumer identification of their therapeutic or natural health products. There is a recognised "…scarcity of empirical research on pharmaceutical packaging and its growing importance in global drug companies' communication…"[933] which also extends to the packaging of CAM products. A meta-analysis of the packaging of both medicines and DSs in one of the biggest online pharmacies in NZ, showed approximately 84% of medicines were packaged in boxes, while nearly 80% of DSs were packaged in bottles.[934] These figures would appear to be consistent with research which shows Europe and the majority of the developed world package 85% of solid medicines in boxes;[935] the notable exception to this rule being the USA, where less than 20% of medicines come in boxes.[936] This supports the theory that consciously or subconsciously, patients are taking account of the packaging when selecting their medicines or DSs; a concerning realisation when considering that high-end DSs appear to favour being packaged and marketed in boxes.[937]

Therapeutic claims have already been discussed in detail,[938] and while the initial theory of these being the leading determinative factor in identification of products has been set aside, they retain an important, yet not exclusive, role in influencing consumer decision making.

Finally, name recognition was added to this chart as the fourth consideration in order of importance. While this may be minimising the effect of name recognition upon people's identification and consequent willingness to buy these products, the survey was not designed to test for this influence, and therefore the only evidence in support of this is largely anecdotal. Name recognition was

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[931] See the studies mentioned in Bernard Roullet and Olivier Droulers "Pharmaceutical Packaging Color and Drug Expectancy" (2005) 32 Advances in Consumer Research 164, at 165 and 169-171.
[932] At 168-169.
[933] At 168.
[934] This data came from a thorough analysis of New Zealand Online Pharmacy Pharmacy Direct "Online Pharmacy | NZ's Leading Online Chemist - Pharmacy Direct" (2016) <www.pharmacydirect.co.nz/>. The analysis was carried out on both the medicines supplied on their website, as well as the large range of CAM products.
[935] Ron Pilchik "Pharmaceutical Blister Packaging, Part I" [2000] Pharmaceutical Technology 68, at 70.
[936] At 70; These studies generally focus on the primary form of packaging for medicines; namely blister packages. Of interest in the present research is the outward appearance of the medicines given that this is what impacts consumers' perspective. Where medicines are packaged in blister packaging, they are then usually always packaged in boxes as the secondary form of packaging to protect the integrity of the blister pack. Roullet and Droulers, above n 931, focuses more on the secondary packaging, although the emphasis in this paper is on colour and its effect on drug expectancy.
[937] See high-end products in ranges like Clinicians, Blis and Blackmores, where more expensive product with fewer tablets or capsules are packaged in bottles which are then put in boxes as a secondary form of packaging for presentation to consumers.
[938] See 9.3.2.

considered a factor for Advil, for despite the brand not being very prevalent in NZ, the active ingredient 'ibuprofen' was identified by a number of respondents when answering question 27, and its effects discussed. Similarly, Folic Acid elicited lengthy responses from a significant number of participants, although this is likely due to a relatively large number of the students coming from science backgrounds. Finally, Probiotics IBS support is likely accompanied by a modicum of name recognition due to the 'trendy' nature of the term 'probiotic' in recent years, resulting in its appearance on a range of food and DS products ranging from yoghurt to cheese to probiotic pickles.

A theory from behavioural economics offers a potential justification for why a combination of these factors may influence consumers to decide a product is something which it is not. Nudge theory stems largely from the exceedingly simplified premise that by nudging people in a particular direction with semi-conscious or subconscious suggestions, you can direct them to behave in a desired manner.[939] A common example of this is placing realistic depictions of flies on men's urinals to improve aim. Application of the theory to the present issue could suggest that through the use of non-verbal marketing, like altering the packaging of DSs such that they come in boxes, and using words more commonly associated with medicines like relief, recovery and pain for example, this may nudge people in the direction of identifying the product as a medicine, or at least believing it to have medicinal properties and consequently be more effective. If further research showed consumers were being 'nudged' towards particular CAM products under the false premises that they were either more effective, or more akin to medicines, then issues may arise on whether this amounts to misleading or deceptive conduct or representations.[940]

The theory discussed above provides a basis for further research, for while it may hold limited evidential or persuasive value on its own merits given the lack of a representative sample and limited number of products studied, it provides scope for more targeted research. These ideas and theories will be will be discussed in more detail at Chapter 10 in the context of a representative study specifically focusing on the packaging and labelling of CAM products.

9.3.4 Environment of sale

The final section questioned participants on the environment of sale and further factors which influenced their decision making. However, the results are broad, and do not deliver any

[939] Richard Thaler and Cass Sunstein *Nudge: Improving Decisions About Health, Wealth, and Happiness* (Yale University Press, New Haven, 2008)
[940] The implications for misleading or deceiving consumers will be considered at Chapter 11.

consequential findings, and therefore in the interests of brevity will largely be set aside, barring two questions: questions 32 and 37.

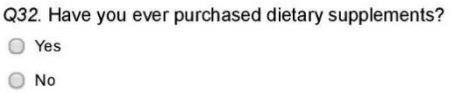

Figure 9.20: Survey 1 - Question 32

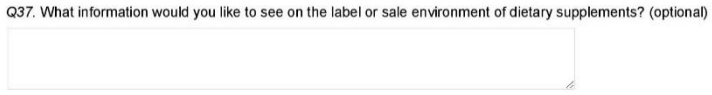

Figure 9.21: Survey 1 - Question 37

Question 32 provides an interesting corollary to questions 9 and 10 on product usage, instead asking here whether participants had ever purchased DSs. Bearing in mind the relatively weak financial position of the majority of respondents, it is rather surprising that 70.7±5.1% of respondents had in fact purchased DSs in the past.[941]

Four themes emerged from the open-ended question 37, in decreasing level of importance; side-effects, readily available scientific evidence, efficacy, and safety. While on first pass, it appears concerning that people are not overly interested in seeing information on efficacy and safety on the label of their products, detailed analysis of the responses indicates that there is a strong desire for reputable scientific information associated with these products to enable consumers to perform their own calculi on whether the efficacy versus safety makes purchasing and consuming the product a worthwhile endeavour. Whether this would actually occur in practice is uncertain. While it is difficult to draw any steadfast conclusions from this question, it does indicate a strong desire from consumers for a greater amount of information associated with their CAM products to allow them to at least have the option of being more informed in their decision making; a laudable desire.

9.4 Conclusion

There is scope for a huge array of studies which build upon the work begun in this survey. However, for the purposes of the present investigation into DS and the effect of their marketing on consumer decision making, there was one natural path to take. On the basis of the results at 9.3.2, and to test the updated hypothesis introduced at 9.3.3, the logical course of action was to conduct a second study which not only sought to answer these questions, but also collected representative data on usage of CAM products in NZ to enable comparison with the rest of the world. This survey and its results will be discussed in Chapter 10.

[941] Comparisons with international data and the results from Survey 2 will be carried out in the following chapter.

10 Packaging of Complementary & Alternative Medicines in New Zealand: A representative study

10.1 Introduction

The previous survey concluded that there were multiple relevant factors informing consumer decision making with respect to their identification of CAM products or medicines. In order of priority, these were listed as; the 'dietary supplement' label, the packaging, TCs, and name recognition. While the 'dietary supplement' label is fairly self-explanatory in terms of its effect, the influence of the packaging and TCs are not as inherently evident. As a result, a new survey was designed which sought to take those two elements and test their effect on consumers' identification of otherwise plainly packaged products. Ultimately, this information will help determine the relative importance of these two factors, as well as provide a springboard from which to assess any FTA implications of misleading or deceptive packaging or statements associated with CAM products at Chapter 11.

Furthermore, this survey provided an opportunity to broaden the scope of its predecessor and take a representative approach; recruiting an array of participants from across the country. Not only did this generate balanced and persuasive results on the perceptions of a cross-section of NZers, it also enabled their usage of CAM products to be studied. The resulting data is unique in that no other recent information exists on NZers purchasing or consumption of CAM products, and consequently, this facilitates a novel comparison with international studies on CAM product usage, whilst demonstrating the prevalence of these products and resultant need for reform.

This Chapter will discuss the findings of this survey, and will suggest that the results reveal a very high level of prevalence of CAM products, and the interwoven nature of TCs and the packaging of CAM products in affecting consumers' perceptions.

10.1.1 Background

The background to the product packaging part[942] of this Representative Study was established through the Pilot Study and its results as discussed above.[943] Consequently, this section considers national and international data on the CAM product usage, in order to put the responses to questions on prevalence in this study,[944] in perspective.

[942] See Questions 9-15, Appendix 4.
[943] See Chapter 9.
[944] See Questions 7-8a, Appendix 4.

In 1997, a National Nutrition Survey was carried out in NZ on people aged 15 years and older, looking at their diet over the past 24-hours, as well as aspects of their diet over the last year.[945] As part of this, information was collected on DS usage, and this was further considered in a secondary analysis some years later.[946] There are issues in comparing this data to the present research given the distinct age range of participants, but nevertheless, it affords a glimpse into consumption habits in 1997, providing a valuable foundation for the present survey to build upon. Of the 4626 respondents, 59% reported using supplements in the past year,[947] while 24.1% of participants noted daily use.[948]

A significant amount of research has been carried out in Australia with respect to the prevalence of CAM usage. While much of this has focused on particular modalities[949] or included CAM practices with CAM products,[950] the South Australian studies[951] have proved a seminal resource in both international study design, and showing the prevalence of these products. In a survey of people 15 years and older, the first South Australian study in 1993 showed a 48.5% incidence of over-the-counter use of CAM products in the previous 12 months.[952] More recent studies suggest that the prevalence has increased to nearer 70% in 2005,[953] although care should be taken in comparing studies whose ambit, with respect to CAM products and modalities, may vary.

In the USA, systematic reviews indicate a high degree of fluctuation between different studies, but nevertheless place CAM usage at an average of 40.5%.[954] Meanwhile the UK shows a greater level of consistency in systematic analyses, with the most recent data indicating 26.3% usage of CAM among the adults surveyed.[955]

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[945] David Russell, Winsome Parnell and Noela Wilson *NZ Food: NZ People. Key results of the 1997 National Nutrition Survey* (Ministry of Health, Wellington, New Zealand, August 1999).
[946] Parnell, Wilson and Smith, above n 881.
[947] At 201.
[948] At 201.
[949] This includes modalities of acupuncture, chiropractic, homeopathy, osteopathy reflexology, massage, or generalised practitioner visits; Harris and others, above n 877, at 93-94; Xue and others, above n 877, at 646-648.
[950] Xue and others, above n 877.
[951] Alastair MacLennan, David Wilson and Anne Taylor "Prevalence and cost of alternative medicine in Australia" (1996) 347(9001) The Lancet 569; Alastair MacLennan, David Wilson and Anne Taylor "The escalating cost and prevalence of alternative medicine" (2002)(35) Preventitive Medicine 166; Alastair MacLennan, Stephen Myers and Anne Taylor "The continuing use of complementary and alternative medicine in South Australia: Costs and beliefs in 2004" (2006) 184(1) Medical Journal of Australia 27.
[952] Harris and Rees, above n 877, at 93.
[953] Xue and others, above n 877, at 643; Roger Byard and others "What risks do herbal products pose to the Australian community?" (2017) 206(2) Medical Journal of Australia 86, at 86.
[954] Harris and others, above n 877, at 930; Data extrapolated from Table 3.
[955] At 930.

A number of systematic reviews of international CAM surveys have been conducted in the past two decades,[956] and all have struggled with the variety of methodologies, not to mention the plethora of modalities which may or may not be included under the umbrella of CAM when surveying members of the public.

10.2 The Representative Study: Methods

10.2.1 Sample & study design

This study is an empirical legal questionnaire study of a cross section of NZers on their usage, and perceptions around the packaging and claims of CAM products. Through primarily quantitative questions which rely on a high degree of subjectivity, this survey reduces products to their most basic level, wherein only the packaging and therapeutic or non-TCs remain, in order to obtain raw data on the effect of these two characteristics upon consumers.

10.2.2 Data collection[957]

This survey was distributed to 2500 NZers who were randomly selected[958] from the NZ Electoral Roll.[959]

Participants were provided with a printed survey and return post envelope, as well as a personalised link to the online survey. Responses were tracked to ensure participants did not respond twice through online and postal formats. The survey was opened on 28 December 2016, and participants were informed they had until 31 January 2017 to respond. Following this, a follow-up letter with the same survey included was sent to 500 people who were randomly selected from those in the initial cohort who had not responded to the first survey. The follow-up letter noted a final closure date of 31 March 2017. To ensure the representativeness of the survey was not affected, no recruitment outside of the postal distribution to the selected 2500 person cohort was conducted.

In total, 573 responses were received. In addition, 44 letters were returned due to failed delivery or incorrect information, and these were removed from consideration of the total distributed. On this basis, the response rate was 23.3%. While this is lower than initially anticipated, it should be viewed in light of a significant period since the last NZ Census in 2013, or general election in 2014 when the

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[956] Harris and Rees, above n 877; Ernst, above n 877; Harris and others, above n 877.
[957] This study received approval from the University of Canterbury Human Ethics Committee on 9 December 2016 (approval reference HEC 2016/68/LR); see Appendix 3.
[958] Randomisation was performed using the random number generator in Microsoft Excel 2013, used under licence to the University of Canterbury.
[959] Permission to use the Electoral Roll was granted under s112 Electoral Act 1993 for the purposes of human health research on 20 December 2016.

information on the electoral roll tends to be the most accurate. Furthermore, the topic may appear abstract due to the nature of questioning on plain packaging, likely leading to a lower response rate.

Nevertheless, on the whole, the demographics of respondents provides a fairly accurate picture of NZers, demonstrating the representative nature of this study. While there is slight variance between the demographic data collected in the survey and data from the 2013 NZ Census,[960] the survey data has not been weighted, as these variations are minor, and selecting a characteristic or characteristics to apply weighting is more likely to add discrepancies to the data considered at 10.3.

Respondents' ages are distributed along the lines of a normal distribution, with a slight shift towards the older age ranges. Nearly 60% of people were aged between 45 and 74, while 34.9% of people were above retirement age. This corresponds with 29.4% of respondents being retired, and generally indicates a trend towards retired, older people having both a greater desire to complete surveys and generally having more time to do so.[961] The female-male divide is slightly exaggerated in the survey compared to Census data, with the survey showing 54.7% females to 45.3% males, while 2013 data is 51.3% females to 48.7% males.[962] Ethnicity data also trended towards an inflated number of NZ Europeans, with 84.3% selecting this option. People who identified their employment status as retired were second only to those who were employed full time (50.6% of respondents). Finally, education level and income levels were both somewhat higher than the NZ average, with 7.1% responding to the survey as having less than a high school education, compared to the NZ level of 20.9% without a formal qualification.[963] Similarly, 17.4% of respondents earned less than $20,000, whereas 38.2% NZers fell into this category, and 5.9% NZers earned more than $100,000 in contrast to the 13.1% who selected this option in the survey.[964]

Despite the survey data not directly correlating to NZ Census data, it is important to recall that this census data is from 2013, and represents all NZers, as opposed to this survey which just sought to survey adults over the age of 18. It should also be noted that this particular topic is unavoidably going to interest respondents who are predisposed to CAM products and modalities, and international

[960] Statistics New Zealand "2013 Census QuickStats about national highlights" (December 2013) <www.stats.govt.nz>.
[961] At 12; Census data would indicate that 14.3% of the population is aged over 65, although this is noted to be on the rise.
[962] At 12.
[963] At 18.
[964] At 23.

studies also show some leaning towards female respondents, often on high incomes, who are well educated.[965]

10.2.3 Questionnaire design

Given the simplified format of the questionnaire[966] compared to the earlier survey, designing this survey was a much more straightforward undertaking.[967] While the material around the packaging and TCs was of somewhat novel design, the questions around prevalence were written in such a way as to make them comparable to international studies so that the incidence of CAM usage in NZ can be juxtaposed with countries like Australia, the USA and the UK.[968]

In order to generate comparable usage data, a number of strategies were implemented from two systematic reviews on CAM usage.[969] Prior to questions on prevalence, the survey provided definitions for both medicine[970] and DS.[971] While ideally, the term 'complementary and alternative medicine' would have been used in this setting, this conflicted with the desire to make the survey relatable for NZers who are accustomed to the term 'dietary supplements' when dealing with the majority of their CAM products. The other primary strategy employed to enable comparison was to question both purchasing as well as consumption of DSs, and in response to a positive answer to the question on consumption, ask about frequency of consumption. Short of considering modalities, this covered all the bases of previously conducted international studies.[972]

To study the packaging and TCs together, a strategy was devised to remove all other features from the products, and to display pictures of packages with and without statements to participants. In an effort to obtain a broad picture of participants' perceptions, two slight variations were developed,

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[965] Ernst, above n 877, at 253 and 255; Parnell, Wilson and Smith, above n 881, at 200; Harris and others, above n 877, at 924-925.

[966] See Appendix 4: Packaging of Complementary and Alternative Medicines in New Zealand.

[967] See 9.2.3.

[968] Three systematic reviews previously mentioned contain all the international studies considered in this thesis, as they ensured consistency with select review criteria and integrity of data analysis in the included studies; Harris and Rees, above n 877, Ernst, above n 877, Harris and others, above n 877. The only other study not included in these reports was Parnell, Wilson and Smith, above n 881. The only systematic review which could have considered this was the 2012 review, and while its failure to be included would indicate it did not meet the standards for inclusion, it is the only NZ study on prevalence prior to the present work, and therefore requires consideration herein.

[969] Harris and Rees, above n 877; Ernst, above n 877.

[970] Appendix 4, Definition of Medicine: "For the purposes of this survey, a medicine is defined as a drug or other preparation for the treatment or prevention of disease."

[971] Appendix 4, Definition of Dietary Supplement: "For the purposes of this survey, a dietary supplement is a product which contains herbs, minerals, vitamins, natural or supplementary nutritional oils or any other product generally considered a complementary or alternative medicine product or a natural health product. Such a product is not a medicine."

[972] Harris and Rees, above n 877, at 92.

with half the participants being shown version one,[973] while the remainder saw version two (see all 12 images at pages 178-179).[974] In total, there were two different boxes and two different bottles, which were displayed with and without statements. There were two claims which were deemed to be TCs, and two which were deemed to be non-TCs. By showing six different permutations in both variation one and two, all possible combinations of claim and packaging were achieved, removing the possibility of bias or internal errors.[975] With the image of the product before them, participants were asked to identify the six images as either a medicine, a DS, or 'other' wherein they were offered the option to comment.

The survey culminated in an open ended option for comment.

10.2.4 Data analysis

All responses to the survey were used for the purposes of analysis at 10.3. While some responses were only partially completed, these were still recorded for the information which they gave.

Statistical guidelines for the analysis of these results was provided by a health-sciences statistician for the earlier survey,[976] and the same parameters were employed in analysis of this survey.[977] The majority of the data in this survey was quantitative, and consequently was analysed using Qualtrics.[978] NVivo complemented manual analysis of responses to the few open-ended qualitative questions in the survey.[979]

10.2.5 Statistics

A normal distribution is used in this analysis to determine the probability of a particular response in the general population, and also to calculate the margin of error on the reported results.

As such, the margin of error is reported on the data as it is presented throughout the results section,[980] based on a normal distribution at a 95% confidence level. The overall standard error of this survey is ±4.09%. As with the Pilot Study, all results are reported to one decimal place unless otherwise noted.

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[973] See Table 10.3 and Figure 10.6: Box_1, TC_1, Figure 10.8: $Bottle_1$, NTC_1, Figure 10.12: Box_2, NTC_2, Figure 10.14: $Bottle_2$, TC_2, Figure 10.10: Box_1, Blank, and Figure 10.11: $Bottle_1$, Blank.
[974] See Table 10.3 and Figure 10.7: Box_1, NTC_1, Figure 10.9: $Bottle_1$, TC_1, Figure 10.13: Box_2, TC_2, Figure 10.15: $Bottle_2$, NTC_2, Figure 10.16: Box_2, Blank, and Figure 10.17: $Bottle_2$, Blank.
[975] See survey at Appendix 2.
[976] See 9.2.4.
[977] See further at 10.2.5
[978] Qualtrics, above n 900, used under licence to the University of Canterbury.
[979] QSR International, above n 906, used under licence to the University of Canterbury.
[980] See 10.3.

10.2.6 Study limitations

The limitations seen in the survey at Chapter 9 were identified and corrected prior to conducting the present study. Consequently, outside of participants' difficulty grappling with the actual material they were being questioned upon, the questionnaire study itself otherwise ran smoothly.

The only real limitations present in the survey relate to the representativeness of the survey, as discussed earlier.[981] While weighting the survey according to NZ Census data would alleviate this issue, it is minor in the context of the data being analysed and consequently, such steps were not taken. Were a further study to be carried out along these lines, researchers should increase the size of the initial cohort. This would raise the number of respondents and reduce the impact from a lack of representativeness.

10.3 Results & Discussion

The results which follow are presented alongside comparisons with other studies and discussion on their ramifications. There are two parts to this section; the first on the prevalence of CAM products, and the second on the effects of packaging and TCs on consumer identification of CAM products.

10.3.1 The prevalence of CAM products

As previously stated, participants were first provided with a definition of DS and medicine to facilitate informed and accurate responses to the questions on prevalence.

Definitions

Medicine: For the purposes of this survey, a medicine is defined as a drug or other preparation for the treatment or prevention of disease.

Dietary Supplement: For the purposes of this survey, a dietary supplement is a product which contains herbs, minerals, vitamins, natural or supplementary nutritional oils or any other product generally considered a complementary or alternative medicine product or a natural health product. Such a product is not a medicine.

Figure 10.1: Survey 2 definitions of Medicine and Dietary Supplement

[981] See 10.2.2.

Q7 Have you ever bought a dietary supplement?

- ❍ Yes
- ❍ No

Q8 Have you ever taken a dietary supplement?

- ❍ Yes *(go to Q8a)*
- ❍ No *(go to Q9)*

If you answered 'Yes' to Question 8;

Q8a How frequently do you take dietary supplements?

- ❍ Daily
- ❍ Weekly
- ❍ 2-3 times per month
- ❍ 1-2 times per month
- ❍ 1-2 times per 6 months
- ❍ 1-2 times per year
- ❍ Less frequently

Figure 10.2: Survey 2 - Questions 7-8a

	Purchased a DS (%) Question 7	Taken a DS (%) Question 8
Yes	79.0±3.3	80.8±3.2
No	21.0±3.3	19.2±3.2

Table 10.1: Survey 2 - Results to Questions 7 & 8 - Responses on purchasing & consumption of CAM products

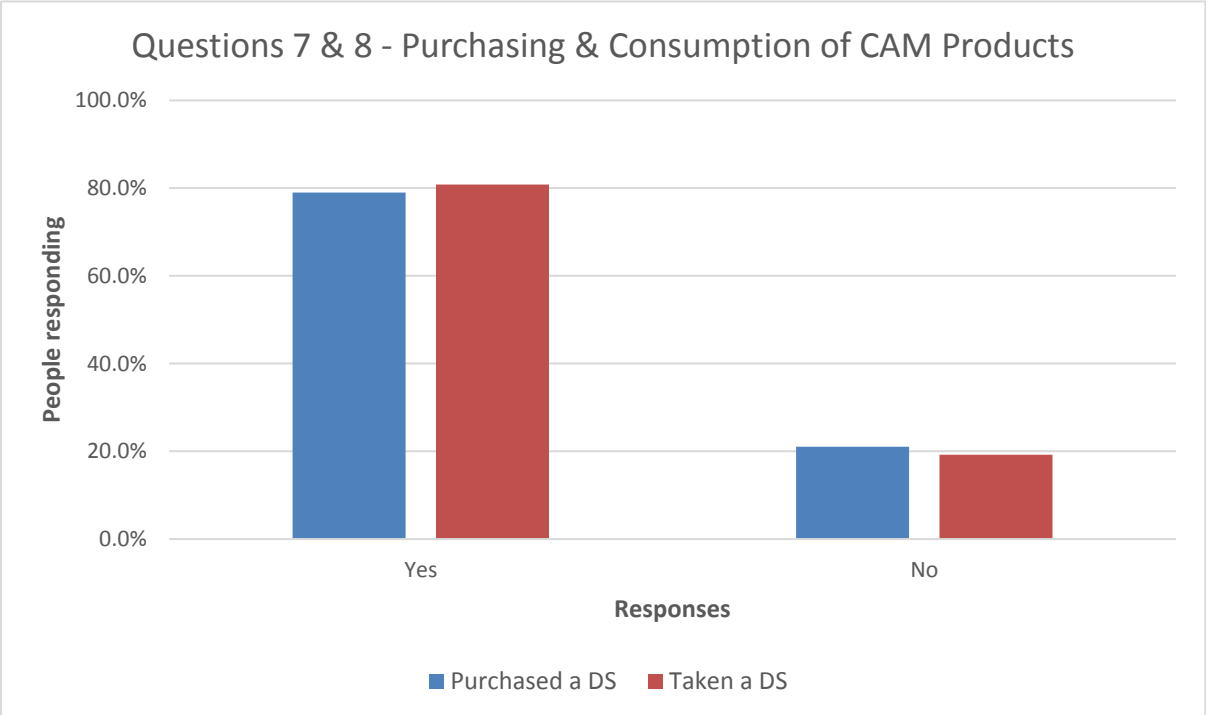

Figure 10.3: Survey 2 - Results from Questions 7 & 8 - Purchasing & consumption of CAM products

Participants were asked both whether they had ever bought a DS, and whether they had ever taken a DS. While this was done partially to ensure maximum comparability with international studies, it also allowed for a comparison between purchasing and consumption trends.

The first point about these results which leaps out is the incredibly high incidence of both purchasing and consuming DSs. NZ usage was estimated to be around 70% prior to conducting this survey from a mix of international studies and the popularity of such products in NZ.[982] As previously mentioned,[983] international studies showed prevalence up to 76%,[984] while closer to home, Australia's prevalence reached a peak of 52.2% in the South Australian studies,[985] or a national total of 68.9%.[986] More than 10 years has elapsed since those studies, and when considered in light of the more relaxed regulatory system in NZ than Australia, and the effect of 'brand NZ' with buzzwords like 'clean, green' and '100% Pure NZ', the basis for this estimation becomes apparent.

Nevertheless, the fact that over 80% of NZers have taken CAM products demonstrates the scale, and consequent importance of this issue in NZ. Figure 10.3 illustrates that the difference between the slightly higher numbers of people who take DSs compared to those who purchase is in fact negligible, especially in light of approximately ±3.3% margin of error in these results.

The second part of the questioning on usage was to study how often those who consume CAM products do so.[987] As such, respondents who answered affirmatively to question 8 were directed to answer question 8a, which asked how frequently they took DSs.

	Frequency of consumption (%) Question 8a
Daily	53.2±4.6
Weekly	9.2±2.7
2-3 times per month	5.5±2.1
1-2 times per month	5.3±2.1
1-2 times per 6 months	6.2±2.2
1-2 times per year	5.3±2.1
Less frequently	15.4±3.3

Table 10.2: Survey 2 - Results to Question 8a - Responses on frequency of consumption of CAM products

[982] See also the one New Zealand study, Parnell, Wilson and Smith, above n 881. While the results are nearly two decades old, they indicated a 59% prevalence of DS use amongst NZ adults aged 15+ years.
[983] See 9.1.1.
[984] Harris and others, above n 877, at 930; see Singapore and Japan.
[985] MacLennan, Myers and Taylor, above n 951; prevalence was 52.2% in the third South Australian Health Omnibus Survey.
[986] Xue and others, above n 877, at 644; Conducted in 2005, this trial showed a peak CAM usage of 68.9% in subjects aged 18+ years.
[987] Question 8a; see Figure 10.2: Survey 2 - Questions 7-8a.

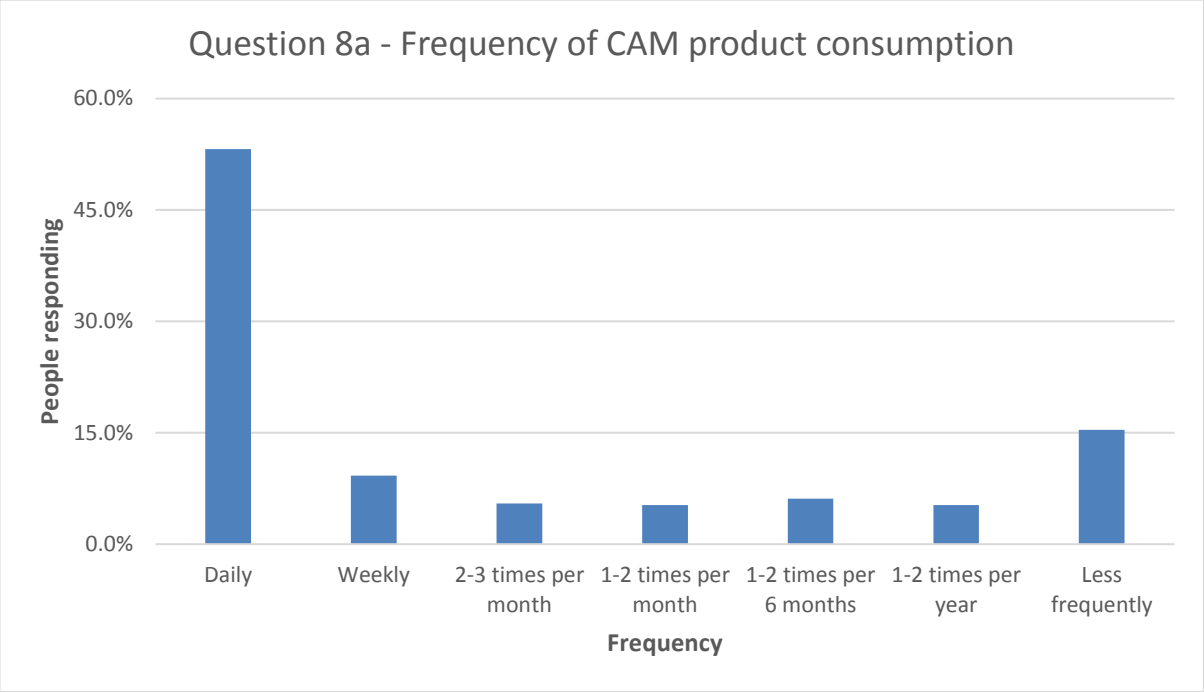

Figure 10.4: Survey 2 - Results from Question 8a - Frequency of CAM product consumption

Importantly, the results showed a high number of people consuming these products daily. In viewing the results in Table 10.2 and Figure 10.4, it is important to appreciate that the results will be slightly skewed by those selecting 'less frequently', as this encompasses those respondents who have taken a CAM product once in the past, or previously used to do so, but have since ceased. When the results from questions 7, 8 and 8a are viewed holistically, they suggest that approximately 43% of NZers consume CAM products on a daily basis.[988] This is an unprecedented level of consumption of CAM products, which while suspected for some time, has until now lacked evidence.[989]

Despite these figures, it is important to bear in mind that there may be a procedural issue with respect to the responses to the questionnaire in that those with an interest in CAM are more likely to respond, and also more likely to consume these products. Nevertheless, the representative nature of the survey attempted to remove the incidence of this error, and the fact that this data largely follows international trends, as discussed above,[990] suggests that it is largely an accurate representation of prevalence in NZ.

[988] This figure of '43% NZers consuming CAM products daily' is extrapolated from the responses to Question 11 which showed 53.2% of the 80.8% of respondents who answered affirmatively to Question 10 were taking CAM products daily.
[989] The highest levels of reported CAM usage in international studies was 76% in Singapore and Japan; Harris and others, above n 877.
[990] See 10.1.1.

In light of the only other NZ research,[991] which showed a 59% usage in the previous year and 24.1% usage in the previous 24 hours, it would appear reasonable that 20 years later, prevalence shows 80.8% of respondents have taken CAM products in the past, while 53.2% imbibe daily.

As an aside, it is interesting to note the similar trend between the histograms in Figure 9.3 and Figure 10.4.[992] In both, there are peaks for CAM product consumption at 'daily' and 'less frequently'. While the frequency of students' consumption at Figure 9.3 is considerably lower for the 'daily' consumption, the results from the two surveys show a similar proportion of people who have previously taken CAM products; with 76.4±4.1% students, and 80.8±3.2% NZers.

10.3.2 Product packaging & therapeutic claims

Background[993]

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other_____

Figure 10.5: Survey 2 - Question format for Questions 13-18

To study the packaging and the claims thereon, two TCs and two non-TCs, and two boxes and two bottles were selected and combined.[994] The claims were printed on plain labels and affixed to the packaging. The finished products are displayed in Figure 10.6 to Figure 10.17.

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[991] See outline of the NZ Nutrition Survey of 1997 as published in Parnell, Wilson and Smith, above n 881

[992] See List of Figures at page x.

[993] Note: The numbering of these questions was inconsistent between version one and version two. The same questions were numbered 9-14 in version one, and 13-18 in version two due to formatting problems with the online survey software. The set of questions will be referred to as 13-18 throughout the results section.

[994] What follows is the wording of the TCs and Non-TCs, and a brief justification for their classification as such:
TC_1: "Relieves cold symptoms | Helps fight common viral infections". For the purposes of comparison and congruence, this was the wording taken from the Olive Leaf product used in the Pilot Study; see Table 9.4 for justification of classification as a therapeutic claim.
TC_2: "Speedy Recovery after sports or injury". For the purposes of comparison and congruence, this was the wording taken from the Arnica product used in the Pilot Study; see Table 9.4 for justification of classification as a therapeutic claim.
NTC_1: "Supports healthy brain and nerve development". For the purposes of comparison and congruence, this was the wording taken from the Folic Acid product used in the Pilot Study; see Table 9.4 for justification of classification as a non-therapeutic claim.
NTC_2: "• Soothes & cools the throat | • Moisturises dry throat | • Pleasant taste". This was the only novel claim used in this study which had not been analysed in the Pilot Study. It was used due to a lack of other suitable claims from the Pilot Study. With respect to its classification as a non-therapeutic claim, the totality of the statement was considered; namely the bullet point format, which tended to indicate a less formal or therapeutic nature. More importantly though, it did not mention a specific problem, disease, medical condition, or explicitly state that it offered relief from any physiological condition as per reg11 DSRs. Furthermore, it does not appear to be hastening healing, but rather is akin to NTC_1 wherein it could equally likely be a label on a beverage as on a CAM product.

In order to a variety of packaging and claim combinations, two alternative versions were created, as seen at Table 10.3. This enables two distinct comparisons; one which studies the effect of different claims when displayed on identical packaging, and the other which studies the effect of different packaging on identical claims.

Figure 10.6: Box_1, TC_1

Figure 10.7: Box_1, NTC_1

Figure 10.8: $Bottle_1$, NTC_1

Figure 10.9: $Bottle_1$, TC_1

Figure 10.10: Box_1, Blank

Figure 10.11: $Bottle_1$, Blank

Figure 10.12: Box_2, NTC_2

Figure 10.13: Box_2, TC_2

Figure 10.14: $Bottle_2$, TC_2

Figure 10.15: $Bottle_2$, NTC_2

Figure 10.16: Box_2, Blank

Figure 10.17: $Bottle_2$, Blank

Effect of different claims on identical packaging

As can be seen in Table 10.3, the same packaging was used between both versions of the survey, but the claim was switched around. For example, Box_1 was part of the question 13 in both versions, but in version 1, it displayed a TC, and in version 2, a non-TC.

	Version 1		Version 2	
	Product	Identification	Product	Identification
Question 13	Box_1, TC_1	Medicine	Box_1, NTC_1	DS
Question 14	$Bottle_1$, NTC_1	DS	$Bottle_1$, TC_1	Medicine
Question 15	Box_2, NTC_2	Medicine	Box_2, TC_2	DS
Question 16	$Bottle_2$, TC_2	DS	$Bottle_2$, NTC_2	Medicine
Question 17	Box_1, Blank	Medicine	Box_2, Blank	Medicine
Question 18	$Bottle_1$, Blank	Other	$Bottle_2$, Blank	Other

Table 10.3: Survey 2 - Results from Questions 13-18

For both questions 13 and 14, the results were unsurprising. Respondents identified the products with the TC 'relieves cold symptoms, helps fight common viral infections' as being a medicine, irrespective of the packaging. Conversely, they identified the packets with the non-TC 'supports healthy brain and nerve development' correctly as DSs, regardless of the packaging.

However, when the results from questions 15 and 16 are considered, the matter becomes less clear-cut. Instead of identifying the two packages with the TC 'speedy recovery after sports or injury' as medicines, participants clearly viewed this as a DS, while they did the opposite with the non-TC; identifying '• soothes & cools the throat • moisturises dry throat • pleasant taste' as indicative of a medicine on both the box and the bottle.

Finally, questions 17 and 18 gave fairly consistent results. The two boxes, when devoid of packaging, both gave consumers the impression of a medicine, while the bottles leave them uncertain, although slightly leaning towards DSs as opposed to medicines.[995]

There are two key findings from the results in Table 10.3. Firstly, the hypothesis that the packaging of the products is determinative as to the contents is clearly incorrect, as seen from the polarised perspectives between versions when the packaging was identical but the claim was different. Nevertheless, this is not to say that the packaging is not having some effect, even if it is not conclusive on its own, as shall be seen below. The second point is that despite a strict legal interpretation identifying 'TC_2' as a TC, and 'NTC_2' as a non-TC, this is evidently not how the public view these claims.[996] This poses a problem in that the line between TCs and non-TCs is so fine that a legal interpretation of these claims is insufficient in determining how the public view them. Therefore, when health-benefit claims are added into the mix, supposedly coming in between TCs, as allowed on medicines,[997] and non-TCs, as allowed on CAM products,[998] this already thin line is set to be broken into pieces, making the situation only more confusing for consumers.

Effect of different packaging on identical claims

Where Table 10.3 considered parallels between TCs and non-TCs on the same packaging, Figure 10.18 and Figure 10.19 turn to look at what effect that packaging is having upon consumer perceptions.

[995] Q18, $Bottle_1$, Blank; Other (41.2±5.8%), Dietary Supplement (30.1±5.4%), and Medicine (28.7±5.3%).
Q18, $Bottle_2$, Blank; Other (41.7±6.1%), Dietary Supplement (32.3±5.8%), and Medicine (26.0±5.4%).
[996] See analysis of TC_2 at Table 9.4: Therapeutic Claims and Misleading Statements, under 'Arnica', and fn 994.
[997] Medicines Regulations 1984, reg8; and Medicines Act 1981, s4; see discussion on therapeutic purpose and the requirement that this be displayed at Chapter 3.
[998] Dietary Supplements Regulations 1985, reg11; see discussion on therapeutic claims and CAM products at Chapter 4.

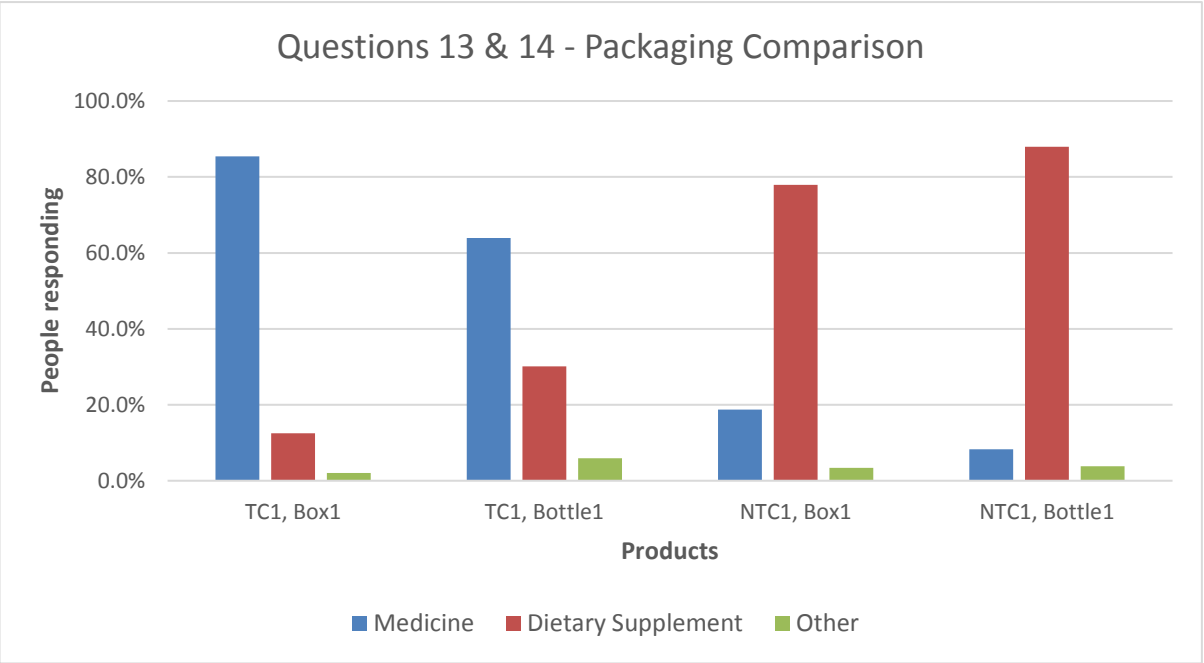

Figure 10.18: Survey 2- Results from Questions 13 & 14

When viewed in pairs, the trend in these results is instantly apparent. The two packets which display TC_1 show that while the majority of participants view both the box and bottle as a medicine, there is a much higher level of certainty among respondents in the case of the boxed product. The same trend is seen in the reverse for the product displaying NTC_1, with the bottled product showing a greater likelihood of being a medicine. The trend continues with the results from questions 15 and 16, and

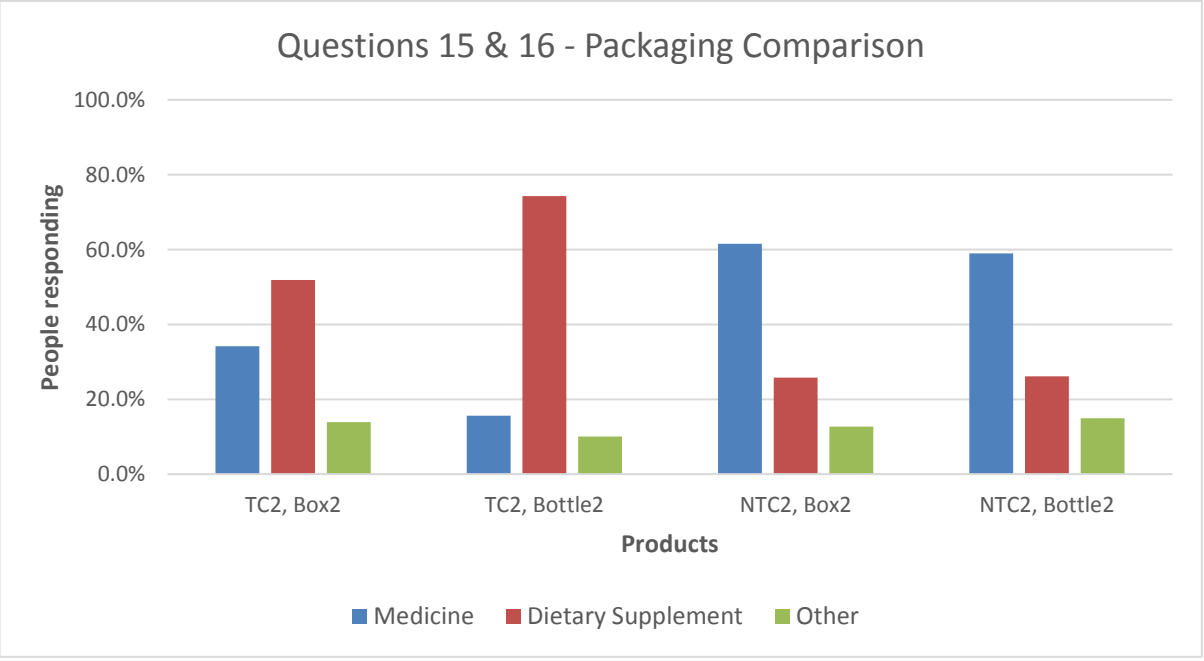

Figure 10.19: Survey 2 - Results to Questions 15 & 16

while difference in the results for NTC_2 is not statistically significant due to being within the margin of error,[999] it nevertheless does not buck the trend.

Despite not altering the outcome in any of these cases, the packaging is still a vital component in consumers' decision making in identifying their medicines and CAM products. It follows, that in instances like those in the first survey, where there was widespread uncertainty as to the identity of some of the products, participants could well be tipped over into a particular identification by such a prominent characteristic as the packaging.

Finally, it is important to look at participants' identification of the plain packaging in questions 17 and 18. What is immediately apparent is the certainty that the box does not represent a DS, but probably contains a medicine in both cases. In both versions, these questions rendered very high 'other' results, which are largely attributable to participants failing to grasp the intent of the question, namely what was more likely to be inside the package, and consequently answering with some variant of 'unknown', 'empty container' or 'no label'. In turn, this skewed the results for the two bottles in question 18. Nevertheless, the confusion regarding the identity of the bottled product remains informative, as it demonstrates that while people will generally instantly conflate a box with a medicine, the same reasoning is not applied to bottles wherein people are probably more likely to take into account additional factors when determining the product's identity.

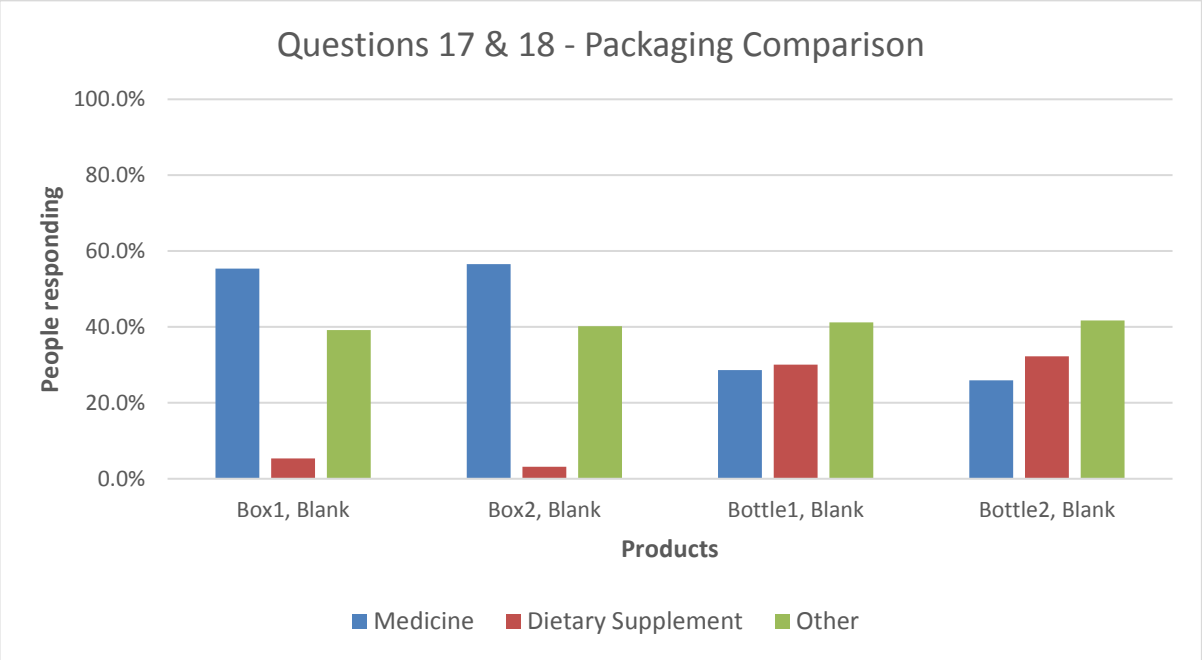

Figure 10.20: Survey 2 - Results to Questions 17 & 18

[999] The difference between those identifying NTC_2 as 'medicine' is 2.6% compared to an average margin of error of ±5.7%.

An holistic overview

Q19 Any other comments or observations on the labeling, packaging or therapeutic claims on medicines and/or dietary supplements? (Optional)

Figure 10.21: Survey 2 - Question 19

Finally, the responses to the open-ended question 19, while not particularly informative, demonstrate the direction of most people's thinking. There were a number of general themes in response to this question. Some people took the opportunity to recount personal information like why they take supplements or medicines, or the kinds and amounts which they consume. Others used the opportunity to comment on the previous questions, with some identifying a theme in terms of packaging, while others talked of the TCs. The final type of responses to this question was those who focused on the problems in terms of regulation or merely what was required on the label. Although some of these people considered this from a perspective of wanting less regulation, the majority of these respondents desired greater information or more stringent regulation to ensure the medicines and CAM products they were consuming were safe and effective.

The totality of this survey's findings on packaging and TCs brings the results of these two surveys full circle. Initially, the TCs were seen to be a determinative factor in the public's identification of CAM products; an hypothesis disproved by the first survey. The second survey subsequently set out to test whether packaging was perhaps solely responsible for incongruous responses in the first survey, and as it eventuates, it does not act alone, but rather in concert with associated elements like the TCs. This dichotomy is best illustrated by considering some comparable results from the two surveys, with the aid of Olive leaf, Arnica and Folic Acid.[1000]

	Complete Packaging (Survey 1)	Box & Claim (Survey 2)	Bottle & Claim (Survey 2)
Folic Acid	DS 93.8±3.6%	DS 77.9±5.0%	DS 87.9±3.8%
Olive Leaf	DS 85.0±5.8%	Medicine 85.4±4.1%	Medicine 63.9±5.7%
Arnica	Medicine 60.8±7.4%	DS 51.9±6.0%	DS 74.3±5.1%

Table 10.4: Comparison between Survey 1 & Survey 2 Products

[1000] These products were three of the six products used in the Pilot Study. As noted at fn 994, the claims from these three products were reused in the present survey to enable the comparison which follows. Table 9.4: Therapeutic Claims and Misleading Statements sets out justifications for classification of the statements as therapeutic claims or non-therapeutic claims, but in summary:
Folic Acid: "Supports healthy brain and nerve development" – a non-therapeutic claim; NTC_1.
Olive Leaf: "Relieves cold symptoms | Helps fight common viral infections" – a therapeutic claim; TC_1.
Arnica: "Speedy Recovery after sports or injury" – a therapeutic claim; TC_2.

Despite differences in survey construction and execution, a comparison of these two surveys immediately illustrates the importance of multiple factors for the public's identification of CAM products. In the case of Folic Acid, a blatant non-TC is barely impacted by removal of other labelling elements, and shows only a slight drop in certainty when packaged in a box. The same cannot be said for Olive Leaf, whose TC overshadows everything else when the 'dietary supplement' tag and other material is removed from the label, with Survey Two unequivocally identifying it as a medicine on the basis of this claim. The opposite is true for Arnica. When the relatively plain logo and product name are removed from the box in survey two, the weak TC is instead considered a DS by a majority in both the box and bottle. This suggests that the public do not view 'speedy recovery after sports or injury' as indicative of a medicine. Instead, in Survey One, the name 'Arnica' or brand name 'Weleda' causes the majority to identify it as a medicine.

10.4 Conclusion

The present research provides a valuable starting point for understanding current NZ CAM product prevalence. Furthermore, the results follow expected trends in light of other countries, with this research showing NZ's usage of CAM products to be higher than most other countries. This is potentially due to nearly a decade between this research and the cited international studies, and also NZ's strong CAM product manufacturing industry; which is likely due to relaxed legislation, and the '100% Pure NZ' or 'clean, green' image.

In many ways, this second survey has confirmed the conclusions of the first survey in a more rigorous and representative manner. Chapter 9 concluded that multiple factors effect consumer decision making, loosely ranking them in order from most important as; the DS label, the packaging, TCs, and name recognition. This study took two of those elements and studied them in isolation, with a variety of results. It demonstrated the interlinked importance of the packaging and TCs, but also the trouble with identifying one as more important than the other. In some cases, the packaging effected more than 20% of respondents in their answers, but TCs and non-TCs tipped the balance of majoritarian identification; just not always in the anticipated direction. At the same time, through comparison to the results of the earlier survey, the importance of aspects like the DS label was further corroborated, as seen in the case of Olive Leaf.

In summary, it is evident from the interplay seen in participants' responses that both the packaging, and the statements displayed on the label are taken into account in identifying the contents. The histograms in this Chapter clearly show the importance of packaging in facilitating this identification, especially in the presence of boxes, while the juxtaposition between TCs and non-TCs in Table 10.3

confirms that in the absence of other material, they are an indispensable aid to consumer identification.

There remains a wealth of further material to study along these lines. The way in which the public interpret TCs, and how they distinguish between TCs and non-TCs remains unclear in light of the results of this survey. Alongside this, there is scope for a consideration of how the public's interpretation of TCs corresponds to a legal interpretation of TCs. What this survey does demonstrate, however, is that both TCs and packaging have an effect on how members of the public identify CAM products and medicines.

11 Misleading or Deceptive Packaging & the Fair Trading Act 1986

11.1 Introduction

Chapter 7 initiated a discussion of misleading and deceptive conduct and representations in the context of the advertising and sale of CAM products. It considered the various sections of the FTA and CGA and suggested that while sections in both Acts were potentially applicable to CAM products, the FTA posed the most likely course of action in terms of the appropriateness of its remedies.

Chapter 11 considers the applicability of the FTA in the context of the packaging of CAM products. This discussion is a consequence of the results of the surveys, as discussed in Chapters 9 and 10, which indicated that packaging may have a material effect upon consumers' identification of CAM products, and their consequent perceptions of those products.

This Chapter discusses whether the packaging of CAM products can in fact be misleading under ss9, 10 and 13 FTA, through an application of the law, as previously considered, to the evidence obtained in the previous two chapters.[1001]

11.2 Liability under sections 9, 10 & 13 Fair Trading Act

Before delving into the central issue of whether packaging can be misleading, it is necessary to briefly establish that the other criteria for ss9, 10 and 13 FTA are met, before proceeding with a discussion on misleading and deceptive (or misleading, or false or misleading) packaging.[1002]

11.2.1 Section 9

Section 9 FTA requires three elements to be proven: the person must be in trade, there must be conduct, and that conduct must be likely to mislead or deceive.[1003]

As discussed at 7.3, 'in trade' has a wide ambit, and therefore the advertising, promotion or sale of CAM products in the packaging in question, as a business activity, or in preparation for a business activity will meet this criteria. Likewise, the advertising, selection of how CAM products will appear

[1001] The CGA is not relevant in this instance, as it concerns guarantees as to the quality and fitness for purpose of the goods; matters which are not an issue in this situation; see 7.9. Nor is s12A relevant, as these are broadly not 'representations' which are capable of being substantiated.
[1002] In the context of packaging, it is unlikely that s12A FTA regarding unsubstantiated representations will be relevant, as misleading packaging is likely to be distinct from more 'normal' representations, as evidenced by the discussions in this Chapter. See 7.7 for more on s12A and unsubstantiated representations.
[1003] See 7.3.

to the consumer, or sale of the CAM products will amount to 'conduct', while the 'misleading or deceptive' requirement will be discussed in more detail below at 11.3 and 11.4.

11.2.2 Section 10

Section 10 FTA also requires three elements to be proven: the person must be in trade, there must be conduct, and that conduct must be liable to mislead as to the nature, manufacturing process, characteristics, suitability for a purpose, or quantity of the goods.[1004]

As for s9, the requirements of s10 around being 'in trade' and engaging in 'conduct' will also be met. Furthermore, there is little question that if misleading conduct is established by the packaging as considered below, it will relate to the 'nature', 'characteristics', or 'suitability for a purpose' of the goods. Finally, it is important to reiterate that the standard in s10 of 'liable to mislead' is lower than that of s9, being 'likely to mislead'.[1005]

11.2.3 Section 13

Section 13 FTA requires three slightly different elements: the person must again be in trade, there must be a representation of the kind listed in subs(a)-(j) that is false or misleading, and that representation must be in connection with the supply or promotion of goods or services.[1006]

The term 'representations' in s13 is narrower than 'conduct' as in ss9 and 10,[1007] but in this instance, the packaging and the language displayed on this is almost certainly a representation as to the goods contained inside, bringing it well within the scope of s13(a), and perhaps even subs(e). Once again, the 'in trade' requirement will be met in this instance, and the mere display of the packaging certainly amounts to the 'promotion' or 'possible supply' of the goods for the purposes of this section. As with s10, the individual requirements of s13(a) and (e) that the goods be misleading as to the 'kind', 'performance characteristics', or 'uses' will be satisfied if the packaging can be found to be misleading as to the identity or efficacy of the goods.

11.3 Can aspects of the packaging be misleading?

Having established that the other requirements of ss9, 10 and 13 FTA are met, the question turns towards whether the packaging itself can be misleading and deceptive. There are two cases in NZ which have considered whether the packaging, or aspects of the packaging can be misleading or

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[1004] See 7.4.
[1005] See 7.4 for a full discussion on s10 FTA.
[1006] See 7.5.
[1007] See 7.5 for a full discussion on s13 FTA.

deceptive; *CC v Reckitt Benckiser (New Zealand) Ltd* concerning the colour of the packaging, and *CC v Sweetline Distributors Ltd* on misleading packaging in the case of slack-fill.

11.3.1 Colour

In *CC v Reckitt Benckiser (New Zealand) Ltd*,[1008] four Nurofen products were labelled as 'Nurofen Migraine Pain', 'Nurofen Tension Headache', 'Nurofen Period Pain', and 'Nurofen Back Pain',[1009] and these all contained statements indicating particular pain relief from the named problems. Additionally, "[t]he specific pain products had different coloured packaging and were frequently sold side by side on stall shelves."[1010] Although Reckitt Benckiser pleaded guilty in this case, the Judge acknowledged the importance of "…the overall impression created by the packaging…",[1011] which suggests that the totality of the packaging, colour, and labelling would be relevant if a similar case were to be decided by the courts.

Reckitt Benckiser pleaded guilty to the charges under s10 FTA relating to misleading representations with respect to their packaging and website,[1012] with the case noting: "RBNZ responsibly accepts the overall impression created by packaging a product that specifically nominated a type of pain was liable to mislead consumers."[1013] Although this case is not decided on the packaging alone, nor does the Judge consider whether the packaging itself is misleading, the acknowledgement of the packaging as a factor in the 'overall impression' that 'was liable to mislead consumers' shows a clear path for the courts' acceptance of misleading packaging in the appropriate case.

11.3.2 Slack-fill

Slack-fill is a form of misleading or deceptive packaging, usually achieved by using a container to make it appear that there are more, or bigger, contents than is actually true.[1014] Slack-fill can still occur when the weight on the product's package is correct, if the information on weight is insufficient to address the overall impression of the size or number of products.

While the issue of slack-fill has not been widely addressed in NZ, it has been raised in a couple of cases, the most pertinent being *CC v Sweetline Distributors Ltd,*[1015] as discussed in detail below. Similar

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[1008] *Commerce Commission v Reckitt Benckiser (New Zealand) Ltd*, above n 708.
[1009] At [5].
[1010] At [6]-[7].
[1011] At [22]-[24].
[1012] At [1].
[1013] At [22].
[1014] Eric C. Wall "A Comprehensive Look at the Fair Packaging and Labeling Act of 1966 and the FDA Regulation of Deceptive Labeling and Packaging Practices: 1906 to Today" (Harvard University, 2002), at 5.
[1015] *Commerce Commission v Sweetline Distributors Ltd* [1993] DCR 817 (DC).

examples arise occasionally, like the recent situation involving Inghams Enterprises and Tegal Foods, where the CC issued a warning over the size of their chickens, which despite containing the correct net weight on the package, was overinflated due to the chickens including marinade and stuffing, rather than just the chicken.[1016]

Slack-fill has been more widely addressed in the USA, which not only has legislation to protect against it,[1017] but also has seen a number of cases around the issue of slack-fill. The majority of these cases relate to food products or consumer toiletries.[1018]

Sweetline is the only case in NZ which not only establishes misleading packaging as an actionable offence under the FTA, but effectively does so on the basis of slack-fill.[1019] Here, the defendant imported and sold Easter eggs in containers similar to that in which poultry eggs are packaged. However, the packages did not contain normal, egg-shaped marshmallow eggs, but instead contained half-eggs, which were flat on one side. While the net weight of the product was correct on the label, there was 67.98% free space inside the packaging.[1020] The CC brought that action under s10 FTA, or s13(a) in the alternative, with the Judge sentencing under s10. In convicting the defendant, the Judge noted that the case relied entirely on the representation made by the packaging, and confirmed that s10 covers virtually the same conduct as s13:[1021]

> In this case it is not suggested that the defendant, or any person on its behalf, made any representation beyond the presentation to its customers of a sample package. That is essentially the same conduct that I have already held amounts to misleading conduct in terms of s10.

The key point from *Sweetline* is that the packaging, in and of itself, was misleading and deceptive under s10 FTA.

11.4 Can the type of packaging be misleading?

Having established that all but the misleading and deceptive elements of ss9, 10 and 13 are met, and following a discussion of the two NZ cases which raise misleading or deceptive packaging, it is now

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[1016] Commerce Commission "Commission issues warning over chicken size representations" (press release, 7 March 2017).
[1017] Federal Food and Drugs Act § 8, 34 Stat. 768 (1906) (USA); Food, Drug, and Cosmetic Act 1938 (USA).
[1018] See Wall, above n 1014, at 7-9 for a discussion on some of these cases, although there have been more recent cases and settlements involving, for example, lip balm (*Ebner v Fresh Inc.* No. SACV 13-477 JVS, 2013 WL 9760035 (CD Cal 2013)), tuna (*Hendricks v StarKist Co.* 13-CV-729 YGR; 2014 WL 1245880 (CA 2014)) and the cases surrounding false bottoms or sides to the container involving Johnson & Johnson and others.
[1019] While the whole case effectively centres around slack-fill, as can be seen from the facts which follow, the exact issue was never named as such in this case.
[1020] *Commerce Commission v Sweetline Distributors Ltd*, above n 1015, at 1.
[1021] At 5.

necessary to turn to the most important question; whether the packaging alone can be misleading or deceptive. This consideration will involve a review of the criteria for misleading and deceptive conduct in line with the *Red Eagle* and *Heaven* tests, followed by an holistic discussion which utilises the survey evidence and the preceding material around the FTA to ascertain whether misleading packaging is a viable course of action.

11.4.1 Misleading packaging in light of *Red Eagle* & *Heaven*

In Chapter 7, the two tests for determining misleading or deceptive conduct were outlined; the three-stage test in *AMP Finance NZ Ltd v Heaven*, and the alternative and simpler approach of *Red Eagle Corporation v Ellis*.[1022] Were a misled individual to take action against a CAM product company on the basis of misleading packaging, the most appropriate test for determining misleading or deceptive conduct would be *Red Eagle*, as it is readily applicable to situations involving a party who has directly suffered loss. However, as with the application of Heaven to MMS,[1023] this matter of misleading or deceptive packaging is not the kind of 'straightforward' case that *Red Eagle* is designed for, and consequently, *Heaven* is a more appropriate test in this instance.

As in section 7.3.2 and 7.3.5 where the test in *Heaven* was applied to the case study of MMS, there are three criteria to meet: whether the conduct is capable of being misleading, whether people are likely to be misled, and whether a reasonable person will be misled by the same conduct.

In applying this test to the abstract packaging issue, it is helpful to use applicable results from the two surveys to ascertain whether the criteria are met. The results in Survey 1 show participants conclusively identifying boxed products as medicines (Figure 9.18).[1024] While Survey 2 shows less of a disparity between participants' identification of boxed and bottled products, there is an undeniable trend for boxes to be more commonly associated with medicines, as demonstrated by the results in Figure 10.20, and more participants identifying boxed products as medicines, than identifying the corresponding bottled product as a medicine (Figure 10.18-Figure 10.19).[1025] This indicates that the conduct of packaging CAM products in boxes may be capable of being misleading.

In addition to substantiating the first criteria, these survey results also show that people are likely to be misled by the packaging of CAM products in boxes.

[1022] See 7.3.2.
[1023] See 7.3.5.
[1024] See page 155.
[1025] See page 182.

The third criteria of the test in *Heaven* is an objective consideration. As noted when this test was used to apply s9 FTA to the MMS case study, the test requires identification of the relevant section of the public and then a consideration of whether members of this group would be misled.[1026] Without an actual case at hand, it is difficult to isolate a section of society. Nevertheless, the surveys provided two particular groups. The Pilot Study showed that a reasonable student could be misled by the packaging, while the Representative Study provided strong evidence for general public being misled by the packaging of products in boxes. On the basis of the evidence in the surveys, there is an arguable case for the packaging being likely to mislead or deceive the reasonable consumer.

11.4.2 A discussion on misleading packaging

Although there is an arguable case for misleading packaging, it is unclear on the currently available evidence whether such a case would succeed.

While misleading CAM product packaging arguably meets the test in *Heaven* and may be likely to mislead consumers, such case would have a greater chance of success by taking an action under s10 FTA due to the lower threshold for 'liable to mislead' under s10, than 'likely to mislead' in s9. If the conduct could be shown to be liable to mislead, there is no doubt that it would be established 'as to the nature of the goods'. Section 13 could be argued in the alternative, although *CC v Reckitt Benckiser* established that misleading conduct in terms of s10 encompassed misleading representations.[1027] Furthermore, both *CC v Reckitt Benckiser* and *Sweetline* were decided under s10, demonstrating the applicability of that section to misleading packaging.

Although both studies would likely be admissible in such a case, their probative value may not be high, as their purpose was for general information gathering with a broad ambit. The two surveys in this thesis would help identify potential misleading and deceptive elements in the advertising and sale of CAM products, and would provide useful evidence in a case, but in seeking a remedy, a directed survey will be more persuasive. For greater applicability to an individual case relating to packaging, a survey would need to be commissioned specifically for that case, to achieve the necessary focus and representativeness.

Considering the bigger picture for a moment, if the CC were to bring an action around CAM product packaging, it is highly unlikely that such an action would be brought in isolation from other elements of the packaging and labelling, which have a combined effect to be misleading and deceptive.[1028]

[1026] See 7.3.5.
[1027] *Commerce Commission v Reckitt Benckiser (New Zealand) Ltd*, above n 708, at [20].
[1028] See the note on the 'overall impression' of the packaging in *Reckitt Benckiser*, above at 11.3.1.

These were discussed at Chapter 9, and include elements like the 'dietary supplement' label, and TCs on CAM products. To take the example of Arnica from the Pilot Study, the combination of a boxed CAM product that is liable to mislead consumers, evidence in the form of the survey which showed consumers being misled into identifying the product as a medicine, and a possible TC on the label, are highly likely to result in an action by the CC under ss10 and 13 FTA being successful.

Although a potential action against misleading packaging under the FTA is a positive enforcement measure, ideally the government would assess the problems like this which permeate CAM product regulation, and ensure new legislation or regulations adequately addresses them such that general legislation does not need to step in where specific legislation is not considered sufficient. This thesis proposes a new regulatory scheme in Chapter 12, and the issue of packaging is included in this proposal.

11.5 Conclusion

This Chapter suggests that the choice of packaging itself may be misleading or deceptive, or at minimum liable to mislead or deceive in contravention of ss10 and 13 FTA. Misleading and deceptive packaging is able to be established through the language of the section, with the aid of the recognised tests for misleading and deceptive conduct, and this approach is not inconsistent with the wording or purpose of these sections. Furthermore, the little precedent which exists in NZ around misleading packaging supports the argument that given the right case, with evidence of misleading conduct like that provided by the two surveys, there may be a good argument for misleading packaging in NZ.

There are not many cases on misleading packaging, but the prevalence of CAM product use as demonstrated in the surveys by the number of people using the products, coupled with their frequency of use suggests that it is only a matter of time before such an issue appears before the NZ courts. Nevertheless, rather than leaving the FTA to pick up the pieces of lacking CAM product legislation, it is recommended that new legislation is considered, which acknowledges the problems at hand with CAM products, and takes steps to address them. This will be discussed in the next section.

Part IV: A New Hope

12 A Proposal for a New CAM Product Regulatory System

This proposal is the pièce de résistance of the entire thesis. It utilises discussion from the preceding chapters in order to design draft legislation which seeks to regulate CAM products now, and into the future. However, this proposal goes beyond merely attempting to regulate in the heavy-handed, over prescriptive manner of previous iterations of CAM legislation like the NHSPB, but aims to put forward a mechanism by which, over time, scientific evidence can be obtained that establishes the efficacy of particular CAM products; ultimately creating a safer, more effective, more transparent marketplace for the benefit of all stakeholders.

This Chapter follows a legislative structure. It begins with a brief commentary justifying the need for a new regulatory regime, then gives an overview of the proposed Bill. There are four parts to this Bill; preliminary matters, a risk-based approach to the regulation of CAM products, the administration of the Bill, and enforcement of the proposed legislation. The Chapter concludes with a brief look at the key provisions to be included in regulations to the Bill, as well as practicalities associated with the enactment of such a system.

For ease of reference, the proposed legislation appears in full in Appendix 5.

12.1 Introduction

12.1.1 Why a new proposal is necessary

There is no question amongst stakeholders that some new form of regulation is necessary; the issue being what form such regulation should take. The current DSRs are so lacking they have been described as tantamount to deregulation.[1029] Even the MoH acknowledges the numerous problems with the existing framework; including the unchecked TCs and misleading information on CAM products,[1030] a systemic lack of information on the safety of CAM products,[1031] a widespread classification issue resulting in a lack of clear delineation between food, medicines and CAM products,[1032] and a regulatory system for CAM products which lags behind most countries.[1033]

[1029] von Tigerstrom, above n 31, at IV.
[1030] Ministry of Health, above n 3, at 4-6.
[1031] At 4.
[1032] At 4.
[1033] At 5.

Various options for reform have been proposed, including a joint trans-Tasman approach to regulation of therapeutic goods,[1034] a permissive approach which effectively allows industry to self-regulate,[1035] continued regulation of CAM products under food legislation,[1036] or regulation of CAM products under medicines' legislation.[1037] The latter two options were considered in the regulatory impact statement for the NHSPB, with this regulatory impact statement ultimately favouring a new option: regulation of CAM products through specific individual legislation.[1038]

It is submitted that specific legislation, as recommended in the regulatory impact statement, is the most appropriate way forward, however this does not mean that the NHSPB should be considered an appropriate model for legislation. The NHSPB attempts to regulate in a reactive manner, imposing strict and uncompromising regulations which leave no room for flexibility to either relax the approach in response to well-researched and effective products, or to draw a line in the sand banning unsafe products with no benefit.

This Chapter will argue that what is needed is an approach that drafts specific legislation for CAM products, and which is proactive in encouraging research into the safety and efficacy of CAM products. This approach regulates on the basis of sound risk assessments and scientific evidence, and incorporates a principle of flexibility to ensure the ongoing relevance and reactiveness of the proposed legislation.

12.1.2 New Zealand's international treaty obligations

It is essential in the design of new legislation for NZ that this is consistent with obligations surrounding existing legislation and international agreements with other countries. This thesis has already considered the primary pieces of legislation which this proposed Bill will affect,[1039] and addresses those interactions where they arise throughout this Chapter. However, it is important to acknowledge key international agreements which may be affected by this proposed Bill,[1040] as well as the defining treaty of NZ's constitutional foundation; the Treaty of Waitangi.

[1034] See 5.3.1.
[1035] See 5.3.4.
[1036] Ministry of Health, above n 3, at 15.
[1037] At 15.
[1038] At 16.
[1039] See Chapters 2-4, and 7.
[1040] In addition to those agreements considered here, there are a number of other international agreements which peripherally affect CAM or pharmaceutical products, like: the NZ-Hong Kong, China Closer Economic Partnership, New Zealand Foreign Affairs & Trade "NZ-Hong Kong, China Closer Economic Partnership" (2017) <www.mfat.govt.nz>; the Association of Southeast Asian Nations (ASEAN), Agreement establishing the ASEAN-Australia-New Zealand Free Trade Area [2010] NZTS 1 (signed 27 February 2009, entered into force 1 January

The Agreement on Closer Economic Relations[1041] between Australia and NZ is noted to be one of the most comprehensive in the world.[1042] Alongside the Closer Economic Relations is the TTMRA codified in the 1997 Act,[1043] which removes restrictions on the free movement of most goods and persons between Australia and NZ.[1044] However, s79 and Schedule 2 TTMRA Act prevent the free movement of therapeutic goods between the two countries,[1045] so unless the scheme this Bill develops is explicitly accepted as commensurate with the Australian regulation of CAM products[1046] and changes are made to the TTMRA Act to reflect this, there will be no substantial effect by this legislation upon NZ's trade agreements with Australia.

The application of the 2008 Free Trade Agreement between NZ and China to CAM products is unclear,[1047] as there is no specific information on these products in the trade deal or associated material.[1048] When considered in light of the strict policy already operated by NZ Customs with regards to the entrance of plant, animal, or food matter into NZ without a licence, it is apparent that this Bill is unlikely to affect the NZ-China free trade agreement in any way.[1049]

The Comprehensive and Progressive Agreement for Trans-Pacific Partnership[1050] (formerly the Trans-Pacific Partnership Agreement[1051]) is a free trade agreement between 11 countries[1052] designed to

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2010); the Australia-USA free trade agreement, Australia-United States Free Trade Agreement [2005] ATS 1 (signed 18 May 2004, entered into force 1 January 2005); the North American free trade agreement (NAFTA), North American Free Trade Agreement (1993) 32 ILM 289 (signed 17 December 1992, entered into force 1 January 1994); the Canada-European Union Comprehensive Economic and Trade Agreement (CETA), Comprehensive Economic Trade Agreement, EU-Canada (30 October 2016); and the European Economic Area (EEA), Decision 94/1/EC ECSC of the Council and the Commission of 13 December 1993 on the conclusion of the Agreement on the European Economic Area [1994] OJ L 1; but these have negligible consequences for NZ CAM product regulation either because NZ is not a party to the agreements, or because the other trade agreements discussed below already impose more rigorous export obligations on NZ.

[1041] New Zealand Australia Closer Economic Relations - Trade Agreement, with Exchange of Letters [1983] NZTS 1 (1 January 1983)

[1042] von Tigerstrom, above n 31, at IV.

[1043] Trans-Tasman Mutual Recognition Act 1997.

[1044] von Tigerstrom, above n 31, at IV.

[1045] Trans-Tasman Mutual Recognition Act 1997, s79 and Schedule 2.

[1046] See 5.3.3 for a brief summary of the Australian system for regulation of CAM products and medicines.

[1047] Shu-Ching Jean Chen "Landmark Trade Deal Struck by China, New Zealand" *Forbes* (7 April 2008).

[1048] Free Trade Agreement Between the Government of New Zealand and the Government of the People's Republic of China [2008] NZTS 19 (signed 7 April 2008, entered into force 1 October 2008).

[1049] New Zealand Customs Service "Prohibited imports" (12 May 2014) <www.customs.govt.nz>.

[1050] Comprehensive and Progressive Agreement for Trans-Pacific Partnership [2017] (not yet opened for signature); as at the time of writing, drafting of the new agreement was underway, with minor adaptations to the earlier iteration, the Trans-Pacific Partnership Agreement, in recognition of the new nature of the agreement since the United States of America had withdrawn from the agreement; see Ministry of Foreign Affairs and Trade "Trans-Pacific Partnership Agreement (TPP)" (2017) <www.mfat.govt.nz/>.

[1051] Trans-Pacific Partnership Agreement [2016] (signed 4 February 2016, not yet in force).

[1052] Australia, Brunei, Canada, Chile, Japan, Malaysia, Mexico, New Zealand, Peru, Singapore, and Viet Nam.

relieve trade tariffs, draw the economies of the countries together, and amongst other matters, harmonise intellectual property regulation between countries to streamline protection of goods.[1053] While the Agreement does not directly address CAM products, issues around pharmaceuticals and intellectual property rights can have flow-on effects for the regulation of CAM products. However, this Bill will not alter intellectual property rights around CAM products; instead leaving any changes in this area to more specialist intellectual property legislation like the Patents Act 2013,[1054] and consequently, this Bill will not affect any of NZ's obligations under this Agreement.[1055]

This Bill recognises the unassailable role that the Treaty of Waitangi plays in NZ's constitutional framework. Although this Bill is focussed on CAM products, and will not regulate the practice of rongoā, or other CAM practices, it is foreseeable that an issue like the commercial production of rongoā products could arise. Therefore, it ensures, through a couple of mechanisms,[1056] that Māori interests and the principles of the Treaty underlie the Bill, and that the recommendations of the Wai 262 report are incorporated, insofar as relevant.[1057]

12.1.3 An overview of the proposed Bill

This proposal recommends regulation of CAM products through an evidential, risk-based approach similar to the FA 2014 and MA, incorporating three tiers for CAM products commensurate with their risk, and the evidence available as to their effects and benefits. Alongside these tiers will be a black-list, which will prohibit ingredients or products known to be dangerous, that also have a risk profile such that they do not merit being in CAM products. To oversee this regime, a regulator would be created, which would oversee pre-approval screening, classification and reclassification of products, and post-market surveillance. The system would be partly government funded and partly industry funded, with a sliding fee scale which promotes safety and efficacy in CAM products through lessened costs depending on the tier classification. The proposal adopts a number of specific policies which

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[1053] Ministry of Foreign Affairs and Trade "Trans-Pacific Partnership Agreement" (2017) New Zealand Treaties Online <www.treaties.mfat.govt.nz>; Benjamin Haas "What is the TPP and is it over? The Guardian briefing" *The Guardian* (22 November 2016).

[1054] Similarly, the Agreement on Trade-Related Aspects of Intellectual Property Rights or TRIPS concerns minimum standards of intellectual property protection between World Trade Organisation members, but as this Bill does not materially affect intellectual property rights or protection for CAM products, it is unnecessary to further consider these agreements; Agreement on Trade-Related Aspects of Intellectual Property Rights (1994) 1869 UNTS 299 (15 April 1994).

[1055] While New Zealand has signed the Agreement, it remains to be seen whether the Trans-Pacific Partnership Agreement will come to fruition, as the President of the United States of America, Donald Trump, signed an executive order on 23 January 2017, withdrawing the USA from the Agreement, and likely signalling a period of deep uncertainty for the future of the Agreement, given the loss of the USA as its primary proponent and biggest economy; Ministry of Foreign Affairs and Trade, above n 1053.

[1056] See 12.2.7 and 12.4 for more information on these mechanisms.

[1057] See Chapter 8 for discussion on the Treaty and the Wai 262 Report.

aim for a more harmonised approach with international regulators in recognition of NZ's size and limited capacity, as well as upholding and respecting the principles of the Treaty of Waitangi and rights of Māori as tangata whenua. Some of the significant provisions of the proposal will be discussed below, while the full draft Bill is included in Appendix 5: The Complementary and Alternative Medicinal Products Bill. Where appropriate, clauses of the Bill footnote or explain comparisons with other legislative provisions which were used in the design and drafting of the particular clause.

12.2 The Complementary and Alternative Medicinal Products Bill: Part 1 – Preliminary provisions

12.2.1 Title

1 Title

This Act is the Complementary and Alternative Medicinal Products Act 2017.

Throughout this Chapter, the proposed Bill will be abbreviated as the CAM Products Bill.

12.2.2 Overview

2 Overview

The CAM Products Bill will adopt an overview clause akin to that in the FA 2014. This will provide an overview on the direction of the legislation, which will potentially be more complicated than the NHSPB due to its thorough, reactive and scientific risk-based approach.[1058]

The Bill will contain four parts. Part one will comprise preliminary provisions around the purpose, principles and definitions of terms in the Bill. Part two will detail the crux of the proposal; the risk-based approach to the regulation of CAM products. Part three will concern the administration of the Bill, outlining the authorities and their functions around the Bill's operation. Finally, Part four will broadly contain enforcement provisions, including offences, defences, and other remedies available under the Bill. There may be additional Parts added relating to export, audit, licensing and other matters, but these will not be discussed here. The Bill will include three schedules; the black-list,[1059] approved international regulators,[1060] and approved published materials.[1061]

12.2.3 Purpose[1062]

3 Purpose

The purpose of this Act is to—

[1058] Compare: Food Act 2014, s3.
[1059] Schedule 1, Complementary and Alternative Medicinal Products Bill 2017.
[1060] Schedule 2, Complementary and Alternative Medicinal Products Bill 2017.
[1061] Schedule 3, Complementary and Alternative Medicinal Products Bill 2017.
[1062] Note: Underlined words or phrases are defined in cl5 CAM Products Bill.

(a) restate and reform the law relating to the sale, marketing, advertising, and trade of complementary and alternative medicinal products; and

(b) achieve safety and quality in complementary and alternative medicinal products; and

(c) regulate complementary and alternative medicinal products in a manner commensurate with the risk of these products, by providing for a risk-based approach that—

(i) minimises and manages the risks to public health; and

(ii) ensures any claims of efficacy are supported by sound scientific evidence; and

(iii) require persons who trade in complementary and alternative medicinal products to take responsibility for the safety and suitability of those products.

Both the FA and the NHSPB include a purpose clause which sets out the direction of the legislation. Rather than adopt a similar succinct statement of purpose to the NHSPB,[1063] the CAM Products Bill has followed the FA 2014, with a relatively detailed purpose clause which focuses on the key characteristics of the Bill which are developed in this Chapter.[1064]

12.2.4 Principles

4 Principles

This Act is based on the following principles:

(a) that the regulation of complementary and alternative medicinal products is managed by a risk-based approach; and

(b) that the regulation, classification, sale, trade, marketing, advertising, decision making and any other matters under this Act are all supported by sound scientific evidence, unless otherwise stipulated in the risk-based approach; and

(c) that the regulation of complementary and alternative medicinal products under this Act favour a flexible approach, where products are reasonably judged on their own merits.

While this Bill will include a principles clause like the NHSPB, it is otherwise quite distinct in its execution. Where the NHSPB principles clause puts forward specific aims of the legislation; for example the information to be included on the label of CAM products and the basis for HBCs,[1065] cl4

[1063] Natural Health and Supplementary Products Bill 2011 (324-2), cl3; "Purpose
The purpose of this Act is to establish a system for the regulation of natural health and supplementary products in New Zealand."

[1064] Compare: Food Act 2014, s4; Natural Health and Supplementary Products Bill 2011 (324-2), cl3.

[1065] At cl4; "Principles
This Act is based on the following principles:
(a) that natural health and supplementary products should be fit for human use:
(b) that the regulation of natural health and supplementary products should be proportionate to the risks associated with their use:
(c) that natural health and supplementary products should be accompanied by information that—
(i) is accurate; and
(ii) tells consumers about any risks, side-effects, or benefits of using the product:

CAM Products Bill will simply posit three foundational propositions intended to underpin the entire legislation.

Firstly, this Bill reiterates the principle of a risk-based approach. While the NHSPB also notes that "…regulation… should be proportionate to the risks…",[1066] its mechanism of achieving such regulation by permitted and prohibited ingredient lists is unlikely to be sufficient.[1067] In contrast, the CAM products Bill develops a detailed and effective plan for managing CAM products in line with their risks. Similar risk-based measures have been demonstrated to be both workable and effective in the FA 2014 and MA.

The second principle of this proposal is its basis in science. A risk-based approach cannot exist without a firm foundation of scientific knowledge upon which to analyse the hazard and exposure and thus determine the risk. Where the NHSPB only looks to make HBCs scientifically supported,[1068] this proposal goes further, requiring scientific evidence to underpin all aspects of the regulation of CAM products under this Bill. It does, however, allow room for traditional evidence to be used in support of tier 3 products.

Thirdly, the principle of flexibility aims to encourage and foster research into CAM products, generally and specifically. Ideally, as a result of this flexibility in the risk-based approach outlined at cl9,[1069] the problems of a lack of information on the CAM product marketplace identified in the regulatory impact statement for the NHSPB can be addressed with additional data and evidence around all aspects of CAM products. A flexible piece of legislation would be perfectly positioned to then respond to these developments, through conventional means of regulations where necessary, but ideally through the decisions and application of the law by the regulatory authority, if the legislation strikes a suitable balance of prescriptiveness such that decisions are fair, while maintaining some flexibility and discretion in its application.

12.2.5 Interpretation

5 Interpretation

In this Act, unless the context otherwise requires, —

(d) the health benefit claims made for natural health and supplementary products should be supported by scientific or traditional evidence."

[1066] At cl4(b).

[1067] See discussion on the permitted and prohibited ingredients lists at 5.6.

[1068] Natural Health and Supplementary Products Bill 2011 (324-2), cl4(d).

[1069] See 12.3.

black-list means the register of prohibited products or ingredients, listed in Schedule 1 and declared by the Regulatory Authority under section 10 to be a prohibited substance on the basis of a risk assessment

The black-list will be discussed in more detail at 12.3.9.

complementary and alternative medicinal product has the meaning given to it by section 6

dietary supplement is a sub-group of complementary and alternative medicinal products that—

(a) is intended to be ingested orally; and

(b) is intended to supplement the amount of amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin normally derived from food products

This definition of 'dietary supplement' is a paired down version of that in both the DSRs and the NHSPB. It clarifies that these products come under the general umbrella of CAM products, but also specifies the products which may be part of this sub-group. This will be discussed further in cl6 under the definition of CAM products.[1070]

efficacy claims are statements on the positive benefits or effects of complementary and alternative medicinal products that—

(a) are prohibited for tier 3 products; but

(b) are permitted for tier 2 products where they—

(i) are supported by scientific evidence; and

(ii) are on prophylactic uses for complementary and alternative medicinal products, including, but not limited to dietary supplementation and nutritional support; and

(c) are permitted for tier 1 products where they—

(i) are supported by scientific evidence; and

(ii) are on prophylactic uses for complementary and alternative medicinal products, including, but not limited to dietary supplementation and nutritional support; or

(iii) are for relief of mild, or low-grade medical conditions; or

(iv) are for symptomatic relief from the effects of mild, or low-grade medical conditions; but

(d) do not include statements that—

(i) claim to cure any medical condition; or

(ii) claim to treat any medical condition; or

(iii) make any reference to acute illness, chronic illness, severe illness, cancer, or any other serious curable, manageable, or treatable medical condition; or

(iv) relate to children, or childhood illnesses in any way

[1070] Compare: Dietary Supplements Regulations 1985, reg2A; Natural Health and Supplementary Products Bill 2011 (324-2), cl5 'dietary supplement'. See 12.2.6.

The term ‘efficacy claims’ was selected as an alternative to ‘therapeutic claims’, ‘therapeutic purposes’, and ‘health benefit claims’ and the confusion the use of these terms has generated. This definition is very detailed, forming one of the key components of the risk-based approach outlined at cl9 below. The ability for products to make efficacy claims as outlined in this definition will be discussed in more detail there, but it is important to briefly highlight sub-cl(d).

By excluding statements of treatment or cure, the definition leaves these as the domain of the MA, where the level of testing and regulation is necessarily higher to reflect medicines’ added risks and benefits. Furthermore, products are prevented from making efficacy claims which provide false hope for serious conditions which can be medically handled in any way; requiring any evidence-based treatment for such ailments to go through the process of becoming a medicine, and thus having regulation commensurate with its risks and benefits. Finally, efficacy claims are prevented on targeting their products towards children, due to the potential for increased susceptibility from harmful side-effects, children’s lack of autonomy, and the need for parents to seek proper medical attention for their children rather than relying on CAM products.

food products—

(a) means any product which has the appearance of food products or drink as they are ordinarily understood; and

(b) either—

(i) is primarily intended for human consumption as food products or drink; or

(ii) is primarily used as an ingredient in food products or drink for human consumption; and

(c) includes—

(i) formulated supplementary sports food as defined by standard 2.9.4 Australia New Zealand Food Standards Code 2002; and

(ii) supplemented food as defined by the New Zealand Food (Supplemented Food) Standard 2016

This definition avoids importing the definition of food from s9 FA due to its broad nature, which would encompass a number of CAM products and their ingredients. Instead, this definition will use the slightly different term of ‘food product’, while also having a narrower scope than ‘food’ in the FA. Consequently, any food under this clause will come within the definition of food in s9 FA.

Although cl6(3) NHSPB employs the concept of defining food by its 'ordinary use',[1071] the CAM Products Bill definition will emphasise, to a greater extent, the importance of the intended purpose or use of the goods, based on the 'ordinary use' template used in the CGA when defining 'consumer' at s2.[1072] This is critical where examples like turmeric or garlic are considered; if they are presented as, or intended for use in, a food or drink, then they should be regulated as a food and not a CAM product.[1073]

> **healthcare advisory statement** is a statement which notes—
>
> (a) if side effects occur, please consult your doctor or pharmacist, and remember to always check with your healthcare professional before mixing medicines and CAM products

This healthcare advisory statement is similar to the warning statements required for medicines under reg13 MRs, albeit less detailed.[1074] This Bill proposes a single, simple statement to appear on every CAM product to ensure people are presented with the same information across the board, and are under no illusions that natural products are ipso facto safe.[1075]

> **herbal medicine or herbal remedy** is a sub-group of complementary and alternative medicinal products that—
>
> (a) includes—
>
> (i) any substance produced by subjecting a plant to drying crushing , or any other similar process; or
>
> (ii) a mixture comprising 2 or more such substances only; or
>
> (iii) a mixture comprising 1 or more such substances with water or ethyl alcohol or any inert substance; and
>
> (b) is not a medicine

[1071] Natural Health and Supplementary Products Bill 2011 (324-2), cl6(3); "In subsection (1), food means anything that is ordinarily used or represented for use as food or drink for human beings."

[1072] Consumer Guarantees Act 1993, s2; "consumer means a person who—
(a) acquires from a supplier goods or services of a kind ordinarily acquired for personal, domestic, or household use or consumption; and
(b) does not acquire the goods or services, or hold himself or herself out as acquiring the goods or services, for the purpose of—
(i) resupplying them in trade; or
(ii) consuming them in the course of a process of production or manufacture; or
(iii) in the case of goods, repairing or treating in trade other goods or fixtures on land"

[1073] Compare: Food Act 2014, s9; Consumer Guarantees Act 1993, s2; Natural Health and Supplementary Products Bill 2011 (324-2), cl6(3).

[1074] The requirement in reg13(1)(i) MRs for warning statements is a general requirement, which is then specified by Medsafe's label statements database; Medsafe "Label Statements Database" (July 2017) <www.medsafe.govt.nz/>.

[1075] Compare: Medicines Regulations 1984, reg13.

This definition will bring herbal medicine or herbal remedy under the present Bill as a CAM product, while also envisaging the definition of herbal remedy being removed from the MA. This definition is largely taken from the MA, however, there remains scope within s3 MA for a herbal remedy to be a medicine where it meets the MA's requirements.[1076]

> **homeopathy** is a sub-group of complementary and alternative medicinal products in which the active ingredient to be administered is in a concentration of not more than 10 parts per million.

This Bill will regulate homeopathy as any other CAM product, although there will be added restrictions on its classification, as discussed at 12.3. The level of 10 parts per million or more dilute was selected as incorporating the majority of homeopathic products, although if new scientific evidence suggested that products more dilute than this level could be effective, then it could be adjusted to reflect this.

> **Minister** means the Minister of the Crown who, under the authority of the Prime Minister, is responsible for the administration of the Act
>
> **medicine**
>
> (a) is a product that—
>
> (i) is used for a therapeutic purpose within the meaning of section 4 of the Medicines Act 1981; and
>
> (ii) the Minister has, under section 20 or 23 of that Act, given consent to its distribution; or
>
> (iii) the Minister is, under section 20(7) of that Act, deemed to have given consent to its distribution; or
>
> (iv) the Director-General, has under section 24 of that Act, given consent to its distribution;
>
> (b) includes—
>
> (i) any related product that the Minister has, under section 20 and 96 of the Medicines Act 1981, given consent to its distribution; or
>
> (ii) any medical device that is the subject of a declaration under regulation 6 of the Medicines (Database of Medical Devices) Regulations 2003

This definition is largely taken from the NHSPB definition of medicine at cl6(2), as it adequately covers all the potential categories of medicines. Additionally, the requirement that a medicine be used for a therapeutic purpose further differentiates it from CAM products, as defined at 12.2.6, which will not be required to have a health benefit. As with the definition of food products above, this definition of medicine aims to avoid cross-over or confusion between food, medicines, and CAM products insofar as practical.[1077]

[1076] Compare: Medicines Act 1981, s2 'herbal remedy'.
[1077] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl6(2); Medicines Act 1981, s3(1).

primary display means the part of a label that is most likely to be displayed, presented, shown, or examined, under ordinary or customary conditions of display for retail sale; and, in the case of cylindrical packaging or labelling, the width of the primary display shall not exceed one-third of the circumference of the package

rongoā Māori means the practice of Māori traditional medicine and is not regulated by this Act where it comes within the scope of complementary and alternative medicine practices at section 6(2); but where traditional Māori remedies are produced on a commercial scale for sale or supply outside the practice of rongoā Māori, this Act will apply as if they are a traditional medicine products

scientific evidence

(a) includes—

(i) randomised, blind, placebo controlled studies; or

(ii) meta-analyses or systematic reviews; or

(iii) reputable scientific texts; or

(iv) sound, peer reviewed research; or

(v) material in reputable peer-reviewed scientific journals; or

(vi) monographs or similar materials from approved international regulators, as listed in Schedules 2 and 3; or

(vii) repeatable experiments; or

(viii) chemical or biological structure modelling; or

(ix) chemical structure-activity modelling; or

(x) verifiable quantitative research; or

(xi) any combination of the above requirements; or

(xii) other material deemed to be sound scientific evidence by the regulatory authority

It is difficult defining what amounts to scientific evidence when it is widely accepted that even the process for obtaining scientific evidence for medicines is systemically flawed. Nevertheless, this list attempts to collate widely accepted sources of scientific information, adding qualifiers in some cases which require a higher standard, but also allow the regulatory agency some discretion in accepting the evidence. Additionally, sub-cl(xii) envisages that early in its establishment, the regulatory authority would establish a set of guidelines relating to the scientific evidence necessary to support classification as a CAM product.[1078]

traditional evidence is evidence of a longstanding history of use of traditional medicine products, commonly sourced from approved published materials listed in Schedule 3

[1078] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl5 'scientific evidence'.

This definition aims to provide flexibility beyond a strict list of pharmacopoeiae, where sufficient evidence is demonstrated by an applicant. It also allows the regulator to exercise some discretion in determining what amounts to a 'longstanding history of use', and how persuasive this information is for the purposes of a product's classification. It is intended that Schedule 3 contain the list of 11 pharmacopoeiae currently in the NHSPB, although a number of these are not available for public access, so the final list of approved sources in Schedule 3 should be reviewed by the regulatory authority.[1079]

> **traditional medicine products** is a sub-group of complementary and alternative medicinal products that—
>
> (a) includes—
>
> (i) any traditional or indigenous medicine which has a longstanding history of use; but
>
> (b) does not include—
>
> (i) rongoā Māori

This definition aims to avoid any debate around traditional versus indigenous medicine by regulating both in the same way as any other CAM product providing they have a history of safe use, which will be employed in the lower tiers, as discussed at cl9. Rongoā Māori is defined separated in this Bill.

12.2.6 Meaning of CAM product

> **6 Meaning of complementary and alternative medicinal product**
>
> (1) In this Act, subject to any specific definition provided for use in another section, **complementary and alternative medicinal product—**
>
> (a) is any product that—
>
> (i) is intended for human use; and
>
> (ii) shows scientific evidence or traditional evidence for its safety; and
>
> (iii) has a risk commensurate with the benefit of the product; and
>
> (iv) is approved for sale and classified by the complementary and alternative products regulatory authority; and
>
> (b) includes—
>
> (i) dietary supplements; and
>
> (ii) herbal medicine or herbal remedies; and
>
> (iii) homeopathy; and
>
> (iv) traditional medicine products products; but

[1079] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl5 'traditional evidence'.

(c) does not include—

(i) any product or ingredient included on the black-list; and

(ii) complementary and alternative medicine practices, or specialist products formulated for an individual patient and dispensed in the course of the practice; and

(iii) any food products, or product presented as a food product; and

(iv) any medicine, or product presented as a medicine; and

(v) any product administered by injection, parenteral infusion, application to the eye, or application to the ear of any human.

(2) In this section, **complementary and alternative medicine practices** means any practice which is not a part of standard medical healthcare in New Zealand.

This definition of CAM product seeks to set defined boundaries for inclusion, while maintaining flexibility. It explicitly excludes foods and medicines in order to clarify the scope of the regulations. While it prohibits certain methods of application on the basis of the risks associated with them, it intentionally does not specify approved methods of application; leaving wide scope for the legislation to encompass a variety of products. With respect to the delineation with food, it is important to note that the phrase 'must not be presented as a food' is taken directly from the NHSPB, and was a specific recommendation from the Health Select Committee.[1080] It enables a line to be clearly drawn between food and CAM products, where the boundaries have often been murky. Finally, this clause incorporates a broad definition for CAM practices; using this to exclude any products created by the practitioner especially for their customer, on the basis of their practice, from regulation as a CAM product within the meaning of this Bill. Most importantly, as seen in the definition of rongoā Māori at 12.2.5, this will exclude Māori traditional medicine in its usual sense from regulation under this Bill.

12.2.7 **The Treaty of Waitangi**[1081]

7 Treaty of Waitangi (Te Tiriti o Waitangi)

In achieving the purpose of this Act, all persons exercising functions and powers under it shall take into account the principles of the Treaty of Waitangi.

12.3 The Complementary and Alternative Medicinal Products Bill: Part 2 – Risk-based approach

8 Overview of this Part

As with the 'Overviews of Parts' in the FA, those in the CAM Products Bill will give an indication of the direction of the following Part. This Part establishes the risk-based approach to CAM product

[1080] Natural Health and Supplementary Products Bill 2011 (324-2) (select committee report), at 4.
[1081] Compare: Resource Management Act 1991, s8; Environmental Protection Authority Act 2011, s4; State-Owned Enterprises Act 1986, s9.

regulation, utilising a table within the legislation in a similar way to the flowcharts in the Income Tax Act 2007,[1082] before going on to set up a framework for the system in the following clauses. There may also be scope for the examples seen in Table 13.1 to be used in the legislation, in a similar way to the Companies Act 1993 or Patents Act 2013.[1083]

12.3.1 A Risk-based approach

Table 13.1 provides an outline of the three tiers, along with a precis of the labelling requirements and evidence requirements for each tier. The examples provided at the end of the table form the basis for a more detailed discussion on the practical application and implementation of the scheme in 12.3.6-12.3.8. This risk-based approach is a pre-approval scheme requiring products to be classified in one of the three tiers prior to being marketed in NZ, and adopts similar tenets to the risk-based measures of the FA 2014 and the MA, in the classification of food sectors[1084] or medicines[1085] respectively, according to their risk.

Table 13.1 is intended to provide a comparative guideline for all stakeholders on the risk-based classification of CAM products. To this end, it could either be included in the legislation or regulations, or alternatively could be published by the regulator as an overview of the system.

[1082] Income Tax Act 2007, Part B.
[1083] Compare: Food Act 2014, s20. See Companies Act 1993, ss199 and 207I; Patents Act 2013, ss11, 15 and 282.
[1084] See 2.4.
[1085] See 3.3.

	Tier 1 Top tier	**Tier 2** Middle tier	**Tier 3** Bottom tier
General	High benefit, low risk	High benefit, Moderate risk Moderate benefit, low risk	Low benefit, very low risk No benefit, very low risk
	Can make strong efficacy claims	Can make weak efficacy claims	Cannot make efficacy claims
	May be required to specify purpose	May be required to specify purpose	Cannot specify purpose
	No packaging restrictions	May be limit on amount of product per package	Products cannot be packaged in boxes
	Lowest annual licencing fees	Moderate annual licencing fees	High annual licencing fees
Labelling Requirements	Labelled with a (green dot) and 'Tier 1 CAM product' on primary display	Labelled with a (orange dot) and 'Tier 2 CAM product' on primary display	Labelled with a (red dot) and 'Tier 3 CAM product' or 'Tier 3 Homeopathic product' on primary display
	Must make healthcare advisory statement	Must make healthcare advisory statement. Must list side-effects	Must make healthcare advisory statement
	Must list all ingredients	Must list all ingredients	Must list all ingredients
Evidence Requirements for Classification	Must supply a copy of the label	Must supply a copy of the label	Must supply a copy of the label
	Must have scientific evidence on safety. Biochemical basis for mode of action and toxicological safety assessments likely required - traditional evidence is insufficient.	Must show sound evidence of safety – traditional evidence unlikely to be enough alone	Must show some evidence of safety – traditional evidence will suffice
	Must show biochemical mode of action, and provide sound scientific evidence for efficacy claims, e.g. monographs, peer reviewed research of clinical studies	Must hold scientific evidence for any efficacy claims. Monographs, peer reviewed research, or clinical studies all accepted. Theoretical basis may be acceptable.	No proof of efficacy required
	Must provide evidence of GMP, Quality Control and product testing	Must provide evidence of GMP & Quality Control plans	Must provide evidence of GMP & Quality Control plans
	Must provide evidence of structural similarity assessments	Must provide evidence of structural similarity assessments	No structural similarity assessment necessary
Examples	Iron products	Olive Leaf	- Arnica 6X Drops (Homeopathic) - Men's Multivitamins

Table 12.1: A Proposed Risk-based Approach for CAM Product Regulation

9 Classification of complementary and alternative medicinal product tiers for purpose of assigning applicable risk-based approaches

(1) The classification of complementary and alternative medicinal product tiers under this Part—

(a) is based on, among other things, the level of risk that their activities pose to public health in terms of the safety and suitability of complementary and alternative medicinal products; and

(b) is for the purpose of ensuring that the information presented to the public on the labelling, packaging and advertising of complementary and alternative medicinal products accords with the risk posed by the particular product; and

(c) is for the purpose of ensuring certainty amongst all stakeholders on the evidential requirements and effect of the classification of complementary and alternative medicinal products on the 3 risk-based tiers.

(2) Accordingly, the regulatory authority is responsible for the classification of individual products into 1 of the 3 risk-based tiers upon application by the manufacturer, importer, or other interested party, in accordance with the measures set out in subsection (3).

(3) The measures referred to in subsection (2) are as follows:

(a) complementary and alternative medicinal products that generally pose a high benefit and commensurately low risk are classified as Tier 1 products; and—

(i) must supply scientific evidence in support of the safety of the product and its effect; and

(ii) are subject to labelling and advertising regulations as appropriate to the individual product; and

(iii) must supply any other material reasonably required by the regulatory authority as stipulated in the regulations to this Act:

(b) complementary and alternative medicinal products that generally pose either a high benefit and commensurately moderate risk, or a moderate benefit and commensurately low risk are classified as Tier 2 products and—

(i) must supply scientific evidence, and where relevant, traditional evidence, in support of the safety of the product and its effect; and

(ii) are subject to labelling, packaging, and advertising regulations as appropriate to the individual product; and

(iii) must supply any other material reasonably required by the regulatory authority as stipulated in the regulations to this Act:

(c) complementary and alternative medicinal products that generally pose either a low benefit and commensurately very low risk, or no benefit and commensurately very low risk are classified as Tier 3 products and—

(i) must supply either scientific evidence, or traditional evidence, in support of the safety of the product; and

(ii) are subject to labelling, packaging, and advertising regulations as appropriate to the individual product; and

(iii) must supply any other material reasonably required by the regulatory authority as stipulated in the regulations to this Act.

Before applying the risk-based approach to three examples which demonstrate the practical application of the system, it is necessary to briefly consider a few parts to the administration of this scheme. The CAM Products Regulatory Authority, as established in cl13, will be responsible for the operation and functioning of this approach, as detailed in cl14.[1086] This will include matters discussed below of the pre-approval scheme, reclassification reviews, post-market surveillance, and management of fees, as well as handling policy-based matters and designing guidelines around product classification, the levels and nature of scientific evidence required for different tiers, and the respective stringency around labelling, packaging and advertising regulations for the different tiers.[1087]

12.3.2 Pre-market approval

The risk-based approach proposed in this Bill will be a pre-approval scheme, where products are required to be classified before being sold or advertised. The NHSPB claimed to be a notification scheme where manufacturers were required to notify the Authority of the products before they were sold. However, with the advent of black- and white-lists in the NHSPB, and limited HBCs for select conditions, this became tantamount to a pre-approval scheme due to the level of restrictions. In contrast, the CAM Products Bill aims to introduce a pre-approval scheme which is considerably more flexible than Australia's system, while upholding the principles of a risk-based approach to ensure safe, high quality CAM products for NZ consumers.

12.3.3 Reclassification reviews

There are two matters to touch upon with respect to reclassification reviews, as included in the Authority's ambit at 12.4.2. Classifications, for which the Authority is responsible,[1088] will last indefinitely providing the licence fee is paid. Instances where reclassification may be necessary will be where there has been a substantial lapse in the licence fee, but the applicant wishes to sell the product again, or where new information or further research has become available, and the applicant wishes to reclassify to a higher or lower tier on this basis.

The second point to note is that licence holders should be aware that each payment of the licence fee constitutes a representation that the information submitted with their initial product classification remains correct. There will be a process stipulated in the regulations for minor changes, like new labelling or other matters which do not require reclassification, but in the event new evidence shows a licence holder's product is not as effective, not as safe, or not of the requisite quality, then such

[1086] See 12.4.
[1087] Compare: Food Act 2014, s21.
[1088] See 12.4.2; cl14(2)(c) CAM Products Act.

matters must be brought to the attention of the Authority, and will likely require reclassification of the product. Failure to do so will amount to an offence.

12.3.4 Post-market surveillance

After its role in classification of CAM products, this proposal envisages post-market surveillance to be one of the biggest responsibilities of the Authority.

Post-market surveillance involves a large number of activities; monitoring the packaging, labelling, and sale of CAM products in a physical setting and in an online setting, ensuring licence holders comply with the terms of their tier, ensuring new research does not contradict the basis upon which licences were granted, ensuring there is no misleading or deceptive conduct or misleading or deceptive representations surrounding the products, and monitoring adverse event reporting.

This Bill will use a similar system to medicines for reporting adverse events; either running the process through the regulator, or outsourcing to a pre-existing agency. For medicines, Medsafe operates an adverse event reporting service,[1089] as does the NZ Pharmacovigilance Centre, which operates the Centre for Adverse Reactions Monitoring out of the University of Otago.[1090] Manufacturers, licence holders, and medical professionals should be obliged to report any adverse effects, no matter how trivial, and consumers should be made aware of the process, and be directed to online forms through which they can submit comprehensive adverse event information.

12.3.5 Costs of the proposal

On costs, this thesis did not set out to provide an economic analysis of existing, proposed, or future CAM product legislation. Earlier versions of CAM product legislation yielded substantial debate in Parliament on the costs of the system,[1091] but as one commentator has observed, NZ has a capacity problem with respect to regulating CAM, and for that matter medicinal products on their own, and as a result any workable system for the regulation of CAM products, will naturally involve significant investment and elevated ongoing costs compared to the status quo.[1092]

This proposal links licencing fees and product classification costs with the risk tier of a product; using costs as an incentivising tool to encourage stakeholders to invest in scientific research into CAM products in order to reduce product licencing costs.

[1089] Medsafe "Report a Problem: Safety Information" (30 May 2017) <www.medsafe.govt.nz/>.
[1090] University of Otago "New Zealand Pharmacovigilance Centre" (2017) <https://nzphvc.otago.ac.nz/>.
[1091] See 5.3.3.
[1092] von Tigerstrom, above n 31.

Although the exact fees will be imposed by regulation, this proposal envisages that the classification fees will be a one-off payment for classification (or reclassification), which recognises the work required to review the products and associated material: a high volume of work to review and classify tier 1 products is matched by a higher classification fee, while a lower classification fee would be set for tier 3 products which are comparatively simple to classify.

In contrast, the annual licencing fees will fund post-marketing surveillance and registration activities by the Authority. These are again commensurate with the work required for products in particular tiers, while achieving a corollary purpose of encouraging product classification in better tiers. Tier 3 products inherently have less benefit, with consequent potential for greater risk and thus require a higher degree of post-marketing surveillance, and thus higher licencing fees in response. Meanwhile, Tier 1 products will have undergone rigorous classification reviews, and with a greater acceptable risk due to their higher benefit, they require less monitoring, and justify lower licencing fees. Ideally, the Authority will set these fees at such a level as to encourage and reward licence holders who undertake work to demonstrate the safety, efficacy, and scientific evidence for their products in order to have their products classified in a better tier.[1093]

12.3.6 An example of Tier 3 products

This clause provides examples of how products meet the requirements for Tier 3 classification under cl9(3)(c)(i), and the consequent obligations to which they are subject under cl9(3)(c)(ii). It concludes by summarising how the products are likely to meet the general classification in cl9(3)(c) as a Tier 3 product. Two products illustrate the dual branches to Tier 3: the homeopathic 'Arnica 6X' as seen in the Pilot Study,[1094] and the Men's Ultivite Multivitamin from the same study.[1095]

For 'Arnica 6X' it is envisaged that a low level of scientific or traditional evidence will be required to demonstrate the safety of the product, in addition to the existence of GMP and quality control plans. In this instance, the applicant would likely be required to show that there was virtually no arnica remaining in the homeopathic mixture,[1096] as well as the fact that the excipients are safe.

[1093] This is similar to the more relaxed packaging and labelling standards which will mirror the licencing fee incentivisation. Higher tiers will have more permissive packaging and labelling regulations, due to the evidence and more acceptable risk profile, in comparison to the more strict regulations envisaged around the packaging and labelling of Tier 3 products. See 12.6 for more on the regulations, and the packaging and labelling suggestions.

[1094] Figure 9.15.

[1095] Figure 9.17.

[1096] A 6X dilution will generally contain one part per million of the active ingredient, which in a volume of 30mL, is tantamount to no active ingredient being present in the substance.

The obligations on the product will likely involve strict labelling and packaging restrictions which clearly show that 'Arnica 6X' is a homeopathic product, no statement of purpose or efficacy claims, no packaging in boxes, and a healthcare advisory statement and list of ingredients displayed on the label. These obligations will be established in the regulations, discussed at 12.4.6 and 12.6.

As 'Arnica 6X' is a homeopathic product, its only option for classification is Tier 3 due to the fact that there is no scientific evidence for the efficacy of homeopathic products, and thus there is no benefit from them beyond the placebo effect.

For Tier 3 classification, Men's Ultivite Multivitamin would need to show low level scientific evidence of the safety of the constituents, negligible risk from the individual products or their combinative effect, and the presence of GMP and quality control processes.

The labelling and packaging obligations would be akin to that for Arnica, except Ultivite would instead state 'Tier 3 CAM Product' instead of 'Tier 3 Homeopathic Product' on the label.

While there is a possibility of a multivitamin like Ultivite achieving Tier 2 classification if the requirements were met,[1097] recent evidence suggests multivitamin supplements provide little benefit in tablet form, as the body is unable to absorb them,[1098] and without this efficacy or benefit from these products, they are unlikely to meet the standard for classification as a Tier 2 product.

12.3.7 An example of a Tier 2 product

As with 12.3.6, this clause also considers the requirements for a Tier 2 product under cl9(3)(b)(i), and the obligations for that product in cl9(3)(b)(ii), before substantiating its proposed classification as a Tier 2 product within cl9(3)(b). This section uses the Pilot Study example of Olive Leaf.[1099]

In addition to requiring scientific and traditional evidence for safety, the requirements in cl9(3)(b)(i) are distinct from that for Tier 3 in that they also require evidence of its effect. The scientific evidence required to classify Olive Leaf as a Tier 2 product will be more substantial than that required for Tier 3 classification.[1100] The applicant for Olive Leaf will be required to hold scientific evidence for all

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[1097] See 12.3.7.

[1098] Coco Ballantyne "Fact or Fiction?: Vitamin Supplements Improve Your Health" *Scientific American* (online ed, USA, 17 May 2007).

[1099] Figure 9.14.

[1100] If approved by the Authority under cls20 or 21, the applicant may be able to rely, in full or in part, upon the monographs prepared by the European Medicines Authority and Health Canada; European Medicines Agency *Community herbal monograph on Olea europaea L., folium* (EMA, online, 22 November 2011); Health Canada *Olive Leaf - Olea europaea* (Heath Canada, online, 8 December 2015).

efficacy claims that the product makes, as well as supplying evidence of structural similarity assessments alongside the evidence for the safety of the product.

In turn, the obligations of the Tier 2 Olive Leaf will be slightly more relaxed than for a Tier 3 product, with weak efficacy claims being permissible where supported by evidence.[1101] The product may be obliged to display a statement to the purpose of the product on the label, and will be required to outline the ingredients, a healthcare advisory statement, and a list of side-effects thereon.[1102] The Authority may also restrict the amount of product permitted in the package if this will lower the risk by reducing an individual's exposure;[1103] limiting the amount of active ingredient per tablet or capsule, limiting the number of tablets or capsules in the container, or limiting both.

Olive Leaf is an excellent example of a Tier 2 product, as it shows some evidence of efficacy as an antioxidant or diuretic,[1104] but there is also evidence of adverse effects associated with its use.[1105] This balance of benefits and risks will likely result in Olive Leaf's categorisation as a product with moderate benefit and low risk, making it suitable for Tier 2 classification.

12.3.8 An example of a Tier 1 product

The requirements and obligations for Tier 1 products again builds upon those for Tier 2,[1106] with the risk-based scheme envisaging that the regulator will require relatively strong scientific evidence at cl9(3)(a)(i), and adopt a permissive approach to labelling and advertising obligations at cl9(3)(a)(ii). In this example, the classification of an iron supplement is considered.

The requirements for the iron supplement to attain Tier 1 classification should be onerous, to ensure that the product is definitely safe and effective. For this reason, scientific evidence alone must demonstrate the safety, mode of action, and efficacy of the product, supported by toxicological and structural similarity assessments. As with the lower tiers, GMP and quality control processes must be demonstrated, as well as the existence of ongoing batch testing to ensure consistently high quality products. The quality and nature of this scientific evidence will be required to be of a higher level than for Tier 2, with the other major difference between the requirements of these two tiers being that the

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[1101] The Authority will be responsible for determining the boundary and establishing guidelines for the difference between weak efficacy claims for Tier 2 products, and strong efficacy claims for Tier 3 products.
[1102] Some of the adverse effects associated with Olive Leaf include allergic reactions, or interactions with pre-existing conditions like heart disease or kidney disorders.
[1103] See Equation 2.1.
[1104] Health Canada, above n 1100, at 2.
[1105] Ian C Shaw "Possible toxicity of olive leaf extract in a dietary supplement" (2016) 129(1432) New Zealand Medical Journal 86.
[1106] See 12.3.7 An example of a Tier 2 product.

applicant must provide the evidence of efficacy for classification in Tier 1, in contrast to merely possessing such evidence in Tier 2.

With a more stringent pre-approval process, Tier 1 products gain less arduous ongoing obligations. As the iron supplement will have demonstrated efficacy through the scientific evidence and pre-vetting of efficacy claims, these claims may be stronger than would be permissible for Tier 2 products. Aside from this, the only other obligations are those of including the green dot symbol and 'Tier 1 CAM Product' on the label, along with the ingredients and a healthcare advisory statement. In some instances, the Authority may require the purpose of the product to be displayed where efficacy claims are not present or the purpose is unclear from the claims.

Iron supplements have a high benefit due to their efficacy in addressing iron deficiency and anaemia. They have a relatively low risk, and coupled with the substantial volume of evidence around their efficacy and safety, the process for Tier 1 classification for these products would be relatively straightforward.

As a brief postscript, this Bill will view food, CAM products, and medicines on a spectrum, where isolated constituents of foods can be CAM products, and the very best CAM products, backed by sound scientific research (like iron supplements) can be mainstream medicines. The three tiers in the CAM Products Bill are a part of this spectrum; an identical product may be classified in different tiers if the applicant either wishes to make different claims for the products,[1107] or merely does not want to provide as much evidence or be subject to as rigorous a review as a higher Tier would demand.

12.3.9 The black-list

> **10 Prohibited products or ingredients**
>
> (1) The Regulatory Authority may, on the recommendation of the Expert Advisory Committee, declare an ingredient or complementary and alternative medicinal product to be a prohibited ingredient or complementary and alternative medicine product, and require that product to be listed in Schedule 1.
>
> (2) …
>
> (3) A declaration made by the Minister under this section must be published on an Internet site maintained by or on behalf of the Authority.

[1107] An example of the same product registered in different tiers would be Vitamin C, otherwise known as ascorbic acid. An applicant may successfully register it in Tier 1 for the relief of scurvy, while another applicant may register the chemically identical Vitamin C product in Tier 2, because they wish to make an efficacy claim for treating colds, where the evidence suggest that Vitamin C is questionably effective for this purpose.

The purpose of the black-list is to prohibit substances whose risk is too high when balanced with the benefit. The list will not ban many of the products that fail to attain Tier 3 status, but will primarily be used to ban dangerous ingredients or excipients like colouring agents which have next-to-no benefit, and fairly strong evidence of risk. Insofar as the process around black-listing of products, this clause provides only a basic framework, which would be expanded upon in the terms of reference for the Authority.

Two examples of products likely to be black-listed are Brilliant black and Tartrazine, which are both on the permitted substances list in the NHSPB, despite their only purpose being as colouring agents, and having substantial evidence for their toxicological effect. While there is evidence that colour plays a role in the placebo effect in pharmaceuticals, this is insufficient a basis to allow colouring agents with a definite risk to be used in CAM products.

The distinction between the black-list here, and the prohibited and permitted substances lists in the NHSPB is that this Bill does not prescribe a white-list, as such a prescriptive approach would contravene the principle of flexibility, unnecessarily restrict CAM products while increasing the regulatory burden, and not achieve any benefit in terms of a risk-based approach.[1108]

12.4 The Complementary and Alternative Medicinal Products Bill: Part 3 – Administration

11 Overview of this Part

This proposal does not intend on putting a rigorous structure in place for the Authority, but to note some key tenets and responsibilities envisaged for the authority under this Bill. [1109]

12.4.1 Transitional provisions

12 Overview of transitional provisions

This proposal then envisages a five year 'grandfathering period', whereby any CAM products which have been registered could be nominally granted tier 3 status for up to five years while they collected the necessary material, and applied for reclassification. After that period expired, any product which had not applied for classification would be struck off, and would have to apply as a new CAM product. During this period, the manufacturers would have to pay the Tier 3 licencing fees, incentivising the

[1108] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl21; Human Assisted Reproductive Technology Act 2004, ss6 and 8.
[1109] Compare: Food Act 2014, s20.

quick collection of information and application for reclassification into one of the higher tiers where appropriate.[1110]

12.4.2 Structure and roles of the Authority and its subsidiaries

13 Complementary and Alternative Medicinal Products Regulatory Authority

(1) This section establishes the Complementary and Alternative Medicinal Products Regulatory Authority (the Authority).

(2) The Authority is the Director-General of Health.

(3) The office of the Authority must be administered by the Ministry of Health.

14 Role of the Regulatory Authority

(1) The Regulatory Authority has the functions, duties, and powers given to it under this Act.

(2) The Regulatory Authority has a role in the complementary and alternative medicinal product regime that includes, without limitation,—

(a) engaging in post-market surveillance of any complementary and alternative medicinal product, including:

(i) monitoring compliance with the applicable requirements of this Act; and

(ii) conducting any testing on complementary and alternative medicinal products to verify their contents, safety, efficacy or veracity of their claims, as appropriate.

(b) co-ordinating the response to emergencies that may undermine the purpose of this Act; and

(c) implementing, managing, monitoring, and auditing the risk-based measures for the safety, suitability, and where appropriate, efficacy, of complementary and alternative medicinal products; and

(d) providing information to the complementary and alternative medicinal product industry and the public on matters relating to the safety, suitability, and where appropriate, efficacy, of complementary and alternative medicinal products; and

(e) establishing and maintaining the public registers; and

…

(l) carrying out any functions that are incidental and related to, or consequential upon, the roles set out in paragraphs (a) to (k).

15 Complementary and Alternative Medicinal Products Expert Advisory Committee must be established

(1) The Authority must establish an expert advisory committee known as the Expert Advisory Committee on Complementary and Alternative Medicinal Products (Expert Advisory Committee).

16 Structure of the Expert Advisory Committee

[1110] Compare: Food Act 2014, s413.

This legislation establishes an Expert Advisory Committee of between 8-12 members with a diverse range of backgrounds which represent the majority of stakeholders, including industry, CAM product, government, consumer, medical, and scientific representatives.[1111]

17 Functions of the Expert Advisory Committee

(1) The Expert Advisory Committee has the following functions:

(a) to collaborate and refer decisions to the Māori Advisory Committee, and take the advice of the Māori Advisory Committee where appropriate on matters involving;

(i) Māori traditional knowledge; or

(ii) Māori traditional medicine; or

(iii) rongoā Māori; or

(iv) any indigenous plant or animal materials.

(b) to issue guidelines and give advice where requested by the Regulatory Authority as to;

(i) the classification of complementary and alternative medicinal products; or

(ii) the requirements of the individual tiers of the risk-based approach; or

(iii) traditional or scientific evidence.

(c) to provide advice to the Authority on;

(i) products or ingredients to be included in the black-list at Schedule 1; or

(ii) international regulators to be approved under section 20; or

(iii) published materials to be approved under section 21.

(d) any other function that the Minister assigns to the Expert Advisory Committee by written notice.

18 Designation of Māori Advisory Committee

A Māori Advisory Committee with expertise in Māori interests, especially insofar as they relate to traditional knowledge, flora, and fauna will be adopted from a pre-established Māori Advisory Committee set up under other legislation.[1112]

19 Functions of the Māori Advisory Committee

The Māori Advisory Committee will provide advice to the Expert Advisory Committee on any matters relating to rongoā Māori, Māori traditional knowledge, and indigenous flora and fauna.

[1111] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl8; Food Act 2014, ss17-19; Human Assisted Reproductive Technology Act 2004, ss27, 32-34.

[1112] Compare: Human Assisted Reproductive Technology Act 2004, ss27-28, and 35.

Clauses 13-19 establish the basic structure for the administration of the Bill, selecting appropriate elements from a range of other legislation.[1113] There are two other branches to the administration of the Bill which bear mentioning. Firstly, the Authority will comprise a substantial body of administrative staff to carry out the day-to-day workings of the Bill. Secondly, there will be an internal appeals board which can handle basic administrative matters which arise from the functioning of the legislation. This will generally be appeals against denied classifications, or other matters related to the ongoing regulation of CAM products.[1114]

12.4.3 Publicly available materials

Alongside its other responsibilities as noted in cl14, the Authority will be required to publish material online for consumers and applicants. In addition to the material in the Schedules to the Bill, there are three key categories which the regulator will need to make available on the internet.

Firstly, there will need to be a searchable database of licenced CAM products, which includes the details relied upon in their classification application, and any of the safety, quality and efficacy information as applicable. Licence holders for Tier 2 products will not have to show their efficacy information here, but if it is not on the packaging or labelling, they will be required to link to evidence of this information on their own internet resources. The second database the regulator is responsible for is one of the scientific and traditional evidence materials relied upon by applicants. While some of this may be available in the database of CAM products, the idea with a source of evidence on CAM products is that this has been reviewed and approved by the authority, and provides a valuable future resource for the public and potential applicants. Furthermore, if there are sufficient resources, the regulator may be able to conduct research on important compounds, the evidence for which can also populate this database. Finally, the regulator will be required to publish all enforcement decisions online. This will take a similar form to the way the CC publishes decisions, and helps to demonstrate enforcement and emphasise the deterrent effect of penalties.

12.4.4 Approved international regulators

20 Authority may declare approved international regulators

This clause allows the Authority to approve similar international CAM product or medicines regulators for particular purposes. It is envisaged that regulators like the Australian TGA, the Natural and Non-prescription Health Products Directorate in Canada, and the European Medicines Agency will be

[1113] Natural Health and Supplementary Products Bill 2011 (324-2), Human Assisted Reproductive Technology Act 2004, Patents Act 1953, Patents Act 2013, Trade Marks Act 2002, Food Act 2014.
[1114] Compare: Environmental Protection Authority Act 2011, s19; Patents Act 2013, s226; Trade Marks Act 2002, s178.

approved regulators. The extent to which the decisions and materials produced by approved regulators are accepted as evidence towards the safety and efficacy of a product will be a case-by-case decision for the Authority with respect to each regulator they approve. Any conditions or limits to approved regulators will be listed alongside their approval status in Schedule 2.[1115]

12.4.5 Approved published materials

21 Authority may declare approved published materials

Much like 12.4.4, this clause allows the Authority to exercise its discretion when allowing published materials to be used as evidence in classification applications or other matters. While materials will not need to be permitted to be used as evidence, this system will provide more certainty for applicants as to the materials which are already approved, and will make the application and classification process easier for both applicant and Authority. Resources like the monographs of the European Medicines Agency, and the pharmacopoeia listed in Schedule 2 NHSPB will likely constitute approved sources, although these will need to be reviewed by the Authority to ensure compliance with the principles of this Bill.[1116]

12.4.6 Regulations

22 Regulations

(1) The Governor-General may, by Order in Council made on the recommendation of the Minister, make regulations—

(a) adding a complementary and alternative medicinal product or ingredient to the black-list in Schedule 1 if the Minister is satisfied that the product or ingredient does not meet the standard for safety under the risk-based approach:

(b) amend Schedule 2 by—

(i) adding an approved international regulator to, or removing an approved international regulator from, the schedule; or

(ii) amending a condition or limit on an approved international regulator in the schedule.

(c) amending Schedule 3 by—

(i) adding an approved published material to, or removing an approved published material from, the schedule; or

(ii) amending a condition or limit on an approved published material in the schedule.

[1115] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl9.

[1116] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl9. A number of the pharmacopoeia listed in Schedule 2 NHSPB are not freely available to the public, and consequently it is difficult to review their contents and make a decision on whether they should be immediately added to Schedule 3 in this Act.

(d) prescribing requirements for the labelling or packaging of complementary and alternative medicinal products; or

(e) prescribing requirements for the advertising of complementary and alternative medicinal products; or

(f) prescribing standards or guidelines for scientific evidence or traditional evidence; or

(g) prescribing standards or guidelines for efficacy claims; or

(h) prescribing standards or guidelines for the classification or reclassification of complementary and alternative medicinal products; or

(i) prescribing the manner in which applications for classification must be made; or

(j) prescribing guidelines on good manufacturing practices and quality control processes for complementary and alternative medicinal products; or

(k) prescribing the requirements relating to access of all publicly available information; or

(l) providing for any other matters contemplated by this Act, necessary for its administration, or for giving effect to any provision of this Act.

This overview of what the regulations will cover is similar to that in cl47 NHSPB. There may be more matters to be added to the list upon completion of the Bill, however it is important that in the final drafting of this clause and in the ultimate creation of the regulations, no Henry VIII power is bestowed by the regulations such that the Minister can override or change the legislation or effect of the legislation by way of the regulations. The material in a couple of these regulations will be discussed in more detail at 12.6.[1117]

12.5 The Complementary and Alternative Medicinal Products Bill: Part 4 – Enforcement

This proposal intends to largely import Part 5 FTA into this scheme to provide for civil and criminal sanctions, as well as defences, and alternative penalties like management banning order, enforceable undertakings, and corrective advertising orders. Although the FTA will remain applicable, it is hoped that this specific regime will take precedence in order to build a clear series of cases to guide manufacturers.

12.5.1 Misleading and deceptive conduct[1118]

23 Misleading and deceptive conduct generally

No person shall, in trade, engage in conduct in relation to complementary and alternative medicinal products that is misleading or deceptive or is likely to mislead or deceive.

24 Misleading conduct in relation to complementary and alternative medicinal products

[1117] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl47.
[1118] Compare: Fair Trading Act 1986, ss9-10.

No person shall, in trade, engage in conduct that is liable to mislead the public as to the nature, manufacturing process, characteristics, suitability for a purpose, or quantity of complementary and alternative medicinal products.

12.5.2 Unsubstantiated, false or misleading representations

25 Unsubstantiated representations

This clause adopts s12A FTA, but focuses the unsubstantiated representations around CAM products and the possible supply or promotion of those products.[1119]

26 False or misleading representations

(1) No person shall, in trade, in connection with the supply or possible supply of complementary and alternative medicinal products or with the promotion by any means of the use of complementary and alternative medicinal products—

(a) make a false or misleading representation that complementary and alternative medicinal products are of a particular kind, standard, quality, grade, quantity, composition, style, or model, or have had a particular history or particular previous use; or

(b) make a false or misleading representation that complementary and alternative medicinal products have any sponsorship, approval, endorsement, performance characteristics, accessories, uses, or benefits; or

(c) make a false or misleading representation with respect to the price of any complementary and alternative medicinal products; or

(d) make a false or misleading representation concerning the need for any complementary and alternative medicinal products; or

(e) make a false or misleading representation concerning the place of origin of complementary and alternative medicinal products.

These clauses are similar to ss12A and 13 FTA, and it is intended that they apply in the same way to CAM products as they do in the FTA. Consequently, cl25 on unsubstantiated representations in this Bill will impose a strict liability offence for CAM products, which will be especially beneficial in requesting further information from licence holders, or penalising licence holders for not holding or publishing material in support of their Tier 2 efficacy claims, for example.[1120]

12.5.3 Offences[1121]

27 Offences

(1) Every person who contravenes a provision of Part 1, Part 2, or sections 24-26 (except section 23), commits an offence and is liable on conviction—

(2) in the case of an individual, to a fine not exceeding $200,000; and

(a) in the case of a body corporate, to a fine not exceeding $600,000.

[1119] Compare: Fair Trading Act 1986, s12A.
[1120] Compare: Fair Trading Act 1986, s13.
[1121] Compare: Fair Trading Act 1986, s40.

28 Defences

(1) Subject to this section, it is a defence to a prosecution for an offence against section 27 if the defendant proves—

(a) that the contravention was due to a reasonable mistake; or

(b) that the contravention was due to reasonable reliance on information supplied by another person; or

The penalties in cl27 will be kept at the same level as in the FTA. While this is higher than in the NHSPB, this is intentional, as any misleading or deceptive conduct with respect to healthcare products should be sanctioned to the highest level. With regards to penalties for the earlier Parts of this Bill, the courts are experienced in using discretion to apportion penalties, and there is no indication in this area of law that a higher maximum penalty set by legislation results in higher fines on offenders.[1122] Additionally, it is important to note that as with the FTA, intention is not necessary in any of these offences, and providing the standard of proof, beyond reasonable doubt, is established, then an individual or body corporate is liable for the sanctions under this clause. Clause 28 also provides for defences to the preceding clause in a similar way to s44 FTA. [1123]

12.5.4 Civil proceedings

29 Injunctions

In much the same way as s41 FTA, this Bill will include the ability for the court to grant injunctions on application of the Authority.[1124]

30 Order to disclose information or publish advertisement

Corrective advertising is a vital tool for addressing misleading and deceptive conduct or representations. This can be extended to specific instances under the present Bill where licence holders have made false efficacy claims, for example, and is an additional tool which allows the Authority to target the enforcement measures to adequately handle the problem, and prevent similar conduct from other manufacturers.[1125]

12.5.5 Enforceable undertakings

31 Enforceable undertakings

[1122] *Commerce Commission v John Graham Godwin and Anor*, above n 161, and *Honey New Zealand (International) Limited v Director General of the Ministry for Primary Industries*, above n 160, are examples of low penalties in this field, when penalising under the Fair Trading Act 1986.
[1123] Compare: Fair Trading Act 1986, s44.
[1124] Compare: Fair Trading Act 1986, s41.
[1125] Compare: Fair Trading Act 1986, s42.

This Bill would introduce enforceable undertakings for lower level offending. In a similar way to which such provisions work in the FTA, the Authority under this Bill may choose to work with the parties to reach a solution as a first resort, rather than immediately turning to prosecution.[1126]

12.5.6 Management banning orders

32 Management banning orders

While they are unlikely to be regularly employed, the adoption of management banning orders into the present legislation is important for its deterrent effect. When directors or managers face the risk of a ban from managing a CAM product company, there is likely to be increased adherence to the legislation and a desire to meet the Authority's standards.[1127]

12.6 The Complementary and Alternative Medicinal Products Regulations

The Authority will be required to design regulations to facilitate the smooth functioning and operation of this Bill, as well as establishing further detail around matters like fees, classification of CAM products, and the labelling and packaging requirements for CAM products. This section does not propose to put forward extensive regulations, but rather to merely posit a few suggestions around the main issues for the CAM Product Regulations.

12.6.1 Labelling

There will need to be extensive regulations around the labelling of CAM products to avoid any indication by manufactures that they are similar to medicines, or more effective than is actually the case. The two studies in Chapters 9 and 10 demonstrated the importance of the labelling informing consumers' perceptions. Notably, the 'dietary supplement' phrase on the primary display was crucial to participants' correct identification of the products as DSs, and the presence of TCs tended to affect consumer identification as to the particular effect of the product. Consequently, both of these elements will be managed in the Bill and regulations. The primary display statement indicating the product's tier coupled with the coloured dot symbol will endeavour to reproduce the effect of the 'dietary supplement' label, while the Bill will take specific measures to remove TCs, and instead introduce the milder, evidence-based efficacy claims to aid consumers with reliable, useful information on their CAM products.

[1126] Compare: Fair Trading Act 1986, ss46A and 46B.
[1127] Compare: Fair Trading Act s46C.

Additionally, there will be regulations around font, label size, location of writing and pictures, and similar matters, in a similar vein to labelling provisions in the Medicines Regulations 1984 and the Smoke-free Environments Regulations 2017.

12.6.2 Packaging

Similarly to the labelling, it is envisaged that there will be substantial regulations around the packaging of CAM products in response to the indications from the quantitative work in Chapters 9 and 10. Those studies demonstrated the previously under-appreciated effect of packaging on the public's identification of CAM products as distinct from medicines. In conjunction with TCs on CAM product labels, boxed CAM products were causing consumers to identify the products as medicines,[1128] and the mere presence of a box, even in the absence of a TC, caused a proportionally greater percentage of the public to identify the product as a medicine, compared to the same product in a bottle.[1129] As a result, the Bill will take a firm stance on managing the packaging of CAM products. The risk-based approach notes that Tier 3 products should not be packaged in boxes,[1130] leaving the regulations to implement this. The other major packaging restrictions proposed in that approach relate to the Authority's ability to restrict packaging size or number of products in a package for Tier 2 products, in order to limit consumers' exposure to the product where necessary. These, and any other provisions that the Expert Advisory Committee recommends around the size, shape, nature and style of the packaging will be part of the CAM Products Regulations.

12.6.3 Good manufacturing practices

One of the roles of the Expert Advisory Committee would be to establish a set of guidelines on GMP. These would likely take a form similar to the CC's fact sheets, which offer generalised information to specific industries or on specific matters.[1131]

Alongside these, there will be regulations which stipulate requirements for manufacturers to ensure suitable manufacture, packing, storage, handling, safety, and quality control measures are in place; similar to those seen in Part 5 MRs.

12.6.4 Advertising

Advertisements for CAM products should be restricted to the material which could be published on the label of the product, and the regulations should reflect this restriction. In a similar manner to Part

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[1128] See Chapter 9.
[1129] See Chapter 10.
[1130] See 12.3.1.
[1131] For example, see the Commerce Commission's fact sheets for the Fair Trading Act; Commerce Commission "Fair Trading Act fact sheets" (2017) <www.comcom.govt.nz/>.

3 MRs applying to medicine advertisements, CAM product advertisements should not be able to refer to official endorsement or approval by the Government, but must note their classification status, healthcare advisory statement, the presence of side-effects where relevant, and may publicise their efficacy claim where permitted by the product's tier. Furthermore, the regulations should ensure that an advertisement of a CAM product makes it abundantly clear to the viewer that this product is a CAM product, and not a medicine.

It may be advisable to the Expert Advisory Committee to develop advertising guidelines, or at minimum work with an advertising body to establish guidelines for CAM product advertising as has occurred with the therapeutic and health advertising code by the Advertising Standards Authority.[1132]

As further information and research is conducted on CAM products and the effects of their labelling, packaging and advertising, the Expert Advisory Committee may decide to put further restrictions in place or relax restrictions if necessary. Furthermore, the Committee should have the ability to recommend alternative labelling, packaging, or marketing devices for communicating the relative ranking of CAM products according to their classification to consumers, if the coloured circle symbol and statement are determined to be ineffective.

12.7 Conclusion

This Chapter has recommended the introduction of a new legislative regime, which will bring NZ's CAM product regulations into the 21st Century.

The scheme implements a risk-based approach to CAM product regulation through the classification of CAM products into three tiers, which account for their risks and benefits and regulate accordingly. The Bill establishes an Authority, whose decisions must be informed by an Expert Advisory Committee, as well as a Māori Advisory Committee in particular instances, with extensive experience in all relevant matters involving CAM products, ensuring all stakeholder voices are brought to the table. The Bill also provides for a broad array of enforcement options similar to those in the FTA, to ensure that an optimal outcome is reached when a breach of the legislation arises.

Finally, this Complementary and Alternative Medicinal Products Bill largely addresses the many failings of earlier legislative proposals, by prioritising consumers and their safety, while still constructing a sustainable and flexible system, which not only encourages and rewards innovation and research, but is structured so as to adapt to the ever-changing CAM product marketplace.

[1132] See 3.3.4.

13 Conclusion

13.1 Introduction

This thesis has proposed a new piece of legislation that provides a light-touch risk-based approach to the regulation of CAM products in NZ, with the goal of increasing the safety, effectiveness and quality of CAM products sold in NZ. The aim of this research was to analyse and critique current and proposed regulations for CAM products in NZ, and on the basis of novel research conducted in the course of this thesis, propose the best option for CAM product regulation in NZ.

This Chapter summarises the preceding 12 chapters, reviewing the history of CAM product legislation, restating the problems this thesis set out to address and outlining the findings from this thesis. It finishes by questioning whether the proposed CAM Products Bill is the best method of addressing the problems facing CAM product regulation, before noting scope for further legal and scientific research in this field.

13.2 Three Decades of the Dietary Supplements Regulations

CAM product regulation in NZ truly began with the regulation of 'herbal remedy' as a medicine within s2 MA 1981. The MA also regulated 'related products',[1133] which importantly includes any food about which a TC is made.[1134] This would later provide an avenue for litigation against CAM products where they made TCs.[1135] In 1985, the DSRs came about under the FA 1981, with the regulations coming into force in 1987.[1136] Thirty years later, the DSRs remain in force, under the new FA 2014.

During this period, multiple proposals for reform of CAM product regulation have come and gone. Between 1999-2014, there were various proposals for a joint regulator of CAM products and medicines between Australia and NZ, although this ultimately failed.[1137] In 2001, an Advisory Committee was established to review complementary and alternative healthcare, with its eventual 2004 report recommending continuing research and development in the healthcare sector to keep pace with the progress in this rapidly changing area.[1138] The Therapeutic Products and Medicines Bill

[1133] Medicines Act 1981, s94.
[1134] At s94(1).
[1135] *Ministry of Health v Pacific Pharmaceuticals Ltd.*, above n 339; *Ministry of Health v Pacific Pharmaceuticals Ltd.*, above n 309; *Zheng v Ministry of Health*, above n 344; *Diet Tea Company Limited v Attorney-General*, above n 346.
[1136] Dietary Supplements Regulations 1985, reg1(3).
[1137] See 5.3.1 The Australia-New Zealand Therapeutic Products Agency (1999-2014).
[1138] See 5.3.2 The Ministerial Advisory Committee on Complementary and Alternative Health (2001-2004).

was introduced in 2006 as an omnibus bill to facilitate the establishment of the ANZTPA as a joint NZ-Australian regulator of CAM and medicinal products, but did not have the support to reach its second reading.[1139] A piece of legislation was proposed by the NZ CAM product Industry in 2009, but this failed to gain traction.[1140] Finally, in 2011, the NHSPB was introduced to Parliament.[1141]

Although the best attempt at CAM product regulation in NZ to date, the NHSPB had a number of issues, perhaps foremost being that it languished in the legislative process for more than six years, and consequently the pre-existing issues of its lack of relevance, and absence of understanding of the CAM marketplace grew more pronounced by the day. With the Health Select Committee reporting back on the Bill towards the end of 2012, the Bill passed its second reading on 20 March 2013. Close to five years have elapsed since that point, until, on 8 November 2017, the Bill was finally withdrawn, and consequently the DSRs continue to regulate CAM products in theory. In practice, these products are effectively unregulated in NZ, with widespread breaches of the regulations acknowledged by the MoH itself,[1142] and the primary means of enforcement being actions by the CC under the FTA.[1143]

13.3 The Problems

As stated in the introduction at Chapter 1, the problems surrounding NZ's regulation of CAM products can be condensed into two broad issues.

The first is the inability of current or proposed legislation to effectively regulate CAM products such that there is clarity around their safety, efficacy, and quality. This issue is exacerbated by ineffective enforcement measures, resulting in the need to use alternative legislation like the FTA.

The second issue is the information deficit around the CAM product market in NZ, usage of CAM products in NZ, public perceptions of CAM products, and the safety and efficacy of CAM products generally. This is closely related to the first issue, as the primary reason for the failure of multiple CAM product regulatory proposals over the past 20-years has been due to a lack of information about the market to be regulated, no comprehension about how wide-spread CAM product consumption is, and little appreciation for the multifarious issues to be encountered when regulating such an area.

[1139] See 5.3.3 The Therapeutic Products and Medicines Bill 2006 (2006-2007).
[1140] See 5.3.4 The 'Joint Industry Natural and Traditional Health Products Bill' Proposal (2009).
[1141] See 5.4-5.6.
[1142] Ministry of Health, above n 3, at 1-5.
[1143] See Chapter 7.

13.4 A Summary of the Findings

There were broadly three aims to the present research: to ascertain the scope and scale of the problems facing CAM product regulation in NZ, to analyse the efficacy of alternative legislation in handling those problems, and ultimately to propose new legislation which would address the identified problems and provide the best solution for managing CAM products. As stated in the introduction, there were three findings which effected the proposed legislation, and ultimately achieved the aims of the research.

13.4.1 The advent of risk-based regulation

Chapters 2 and 3 served a dual purpose. Firstly, they established the background to CAM product regulation by discussing the parallel legislation governing food and medicines. Arguably more importantly, they set the scene for a comparison of any legislation regulating products for human consumption, with the gold standard of risk-based approaches to product regulation. The MA 1981 led with a remarkably prescient approach, which was followed in a similar manner by the FA 2014. These examples of risk-based measures provided a stark contrast to the regulation in the DSRs, and although the NHSPB claims to establish a risk-based system,[1144] the reality is that the Bill takes little to no account of risks and associated benefits of products and ingredients,[1145] instead regulating in a somewhat haphazard and directionless manner.

13.4.2 The blind leading the blind: a lack of comprehension or direction in CAM product regulation

The many shortcomings of the DSRs outlined in Chapter 4 could be forgiven in 1985, when CAM products were a niche item, and primarily did comprise DSs. However, in light of their more widespread use, general acceptance, and the plethora of available products encompassed in the term 'CAM products' today, the continued existence of the same regulations in 2017 is a serious problem. Throughout all the attempts at replacing the DSRs, as outlined in Chapter 5, the clear problem is a lack of direction and no strong vision for the future. As such, there has been, at best, lacklustre support for any of these reforms. Whether it is the reason for the lack of direction, or a symptom of it, the defining problem plaguing reform is the absence of sound empirical data on the safety, efficacy, use, quality, and public's perceptions of CAM products. Chapter 6 emphasised how the irrelevance of the DSRs, coupled with failure of any measures for reform results in products like MMS effectively having free reign with respect to product safety, and claims about the product.

[1144] Natural Health and Supplementary Products Bill 2011 (324-2), cl4(b).
[1145] For example, see 5.6.4 and discussion on colouring agents permitted in NHSPB.

13.4.3 Analysis of the problems: their scale, scope and the use of alternative legislation

The example of MMS from Chapter 6 and the broad failure of food, medicine, or CAM product legislation to handle this issue was a stark contrast to the FTA's ability to address the problems of misleading and deceptive conduct and false representations. Chapter 7 clearly demonstrated why the FTA has become the only successful enforcement measure against CAM products, and while having some means of enforcement is a step in the right direction, the use of consumer protection legislation to address a fraction of the misleading conduct associated with CAM products is a far cry from an optimal solution. Chapter 8 addressed a slightly separate problem, but nonetheless one at the forefront of a CAM product regulatory scheme for NZ: the place of the Treaty of Waitangi and the recommendations of the Wai 262 report on TM. It is telling of the systemic flaws in the NHSPB that it fails to even recognise the Treaty, despite its immediately apparent relevance to this area of law.

Chapters 9 and 10 set about addressing the second major problem; that of the information deficit. These empirical studies focused on the prevalence of CAM product usage among NZers, and consumer perceptions of CAM products. While only the tip of the iceberg around the information necessary to effectively regulate, these studies established the raw scale of CAM product consumption among NZers, with findings suggesting that 80% consume CAM products, and 50% of those do so on a daily basis. They also highlighted the factors involved in misleading consumers around the identity of CAM products and their efficacy, prompting the question in Chapter 11 of whether the packaging of CAM products can be misleading or deceptive within the FTA. This discussion again demonstrated the broad application of the FTA to issues involving CAM products, with the result being that the FTA's enforcement measures and provisions around misleading and deceptive conduct and false representations were built into the CAM Products Bill in Chapter 12, given their history of use in CAM product cases, and efficacy in handling such matters.

13.4.4 Options for the regulation of CAM products

With this background and empirical work explained, the thesis considered three options for the regulation of CAM products going forward: the status quo of the DSRs, the NHSPB, or the proposed CAM Products Bill in Chapter 12.[1146]

There is almost unanimous agreement among stakeholders that the status quo is unacceptable and change is necessary. The NHSPB was undoubtedly more appropriate than the DSRs, but was ultimately unwieldly, and lacked understanding of the market it was trying to regulate. It arguably polarised the industry, while still failing to adequately protect consumers and ensure the availability of safe,

[1146] See the full Bill; Appendix 5: The Complementary and Alternative Medicinal Products Bill.

effective, and quality products. On the basis of the arguments raised throughout this thesis, the CAM Products Bill proposed herein is posited as the best solution currently available for the regulation of CAM products in NZ.

13.5 Does the CAM Products Bill adequately address the problems?

If the CAM Products Bill is to be recognised as the best option for the future of NZ CAM product regulation, then it must, at minimum, address the problems plaguing CAM product regulation that this thesis has highlighted.

By adopting various elements from different pieces of legislation which have proven effective in similar situations (for example the risk-based approach in the FA 2014, and the enforcement measures in the FTA), the CAM Products Bill endeavours to create one piece of legislation which will regulate CAM products without substantial reliance on more general legislation. At the same time, the risk-based approach which underpins the Bill prioritises safety, quality, and efficacy in CAM products, with scientific evidence being encouraged and rewarded within this scheme. As such, the CAM Products Bill addresses this issue head-on, resulting in a Bill that will provide clarity and relative simplicity to consumers, industry, and government alike.

With the benefit of knowledge gained from two empirical studies providing additional information around CAM products, this Bill is already in a better position to address the information deficit than other proposals. The Bill was constructed with an appreciation for the huge market, which currently exhibits major problems around misleading consumers as to the nature and efficacy of CAM products. Consequently, knowing the market size, this Bill is able to regulate to an appropriate level, while taking account of problems like misleading packaging, and implementing measures to prevent this from continuing (like prohibiting Tier 3 products from being packaged in boxes). At the same time, the Bill acknowledges the substantial information still to be gathered around CAM products in NZ, and allows sufficient flexibility in its regulation to manage unknown current problems, and future problems as they arise in the course of ongoing research.

Finally, the Bill ensures additional issues raised in the course of this thesis are handled, including rongoā Māori and the Treaty of Waitangi. This Bill proposes tried, workable, and readily implementable systems derived from a wide assortment of legislation, to enable straightforward passage through Parliament so as to begin the process of regulating NZ's CAM product marketplace in a manner befitting the 21st Century.

13.6 Further Research

This thesis took a broad approach to researching CAM product regulation from both a scientific and legal perspective. It considered a raft of relevant legislation, in addition to conducting empirical work, which in turn raised issues of misleading and deceptive practices surrounding CAM products. Nevertheless, there remains a significant amount of legal and scientific research to be conducted in this area.

Building upon the research and findings of this thesis, further legal research could be conducted into intellectual property considerations around CAM products, with an especial focus on strategies for the protection of traditional medicine and associated traditional knowledge. This thesis also enables detailed reviews of CAM product regulations in different countries, with potential starting points being comparisons between the USA and NZ's DSRs, Canada and NZ under the NHSPB, and between Australia and NZ; although consideration of China, Hong Kong, the European Union and the UK would provide a varied global perspective.

While further scientific research could be conducted into perceptions of CAM products, and the effect of packaging, advertising and labelling upon consumers, this would be best conducted in response to a particular case requiring evidence of misleading and deceptive conduct as noted at 11.4.2. Instead, the two directions for scientific research would be to study the active ingredients, mode of action, and efficacy of common CAM products, or to conduct a wide scale study in NZ similar to the Newmaster research discussed at 4.5.2, that analyses the actual constituents of CAM products in NZ, the accuracy of the listed ingredients, and the presence of contaminants, fillers, or other materials within CAM products.

13.7 Concluding Remarks

To return to the question posed at the very beginning of this thesis; why does the regulation of complementary and alternative medicine products matter?

CAM product regulation matters to the 80% of NZers who have taken CAM products. NZ is renowned for its socialised healthcare, with publicly funded hospital care, accident coverage, and subsidised medicines, but it is out of step to have effectively unregulated CAM products readily available to the public. Where those 80% of people trust the government sufficiently to regulate their foods and medicines, they should also know that at minimum, the safety and quality of their CAM products is ensured through sound regulation.

CAM product regulation matters to all NZers, because no-one should be misled or deceived by false or misleading CAM products. No-one should blindly be left to rely on representations made on a product as to its safety, efficacy, or quality with no way of knowing the veracity of the representations, or lack thereof. CAM product regulation should matter to everyone, as additional research, development, and investment into CAM products will only yield positive outcomes; removing ineffective or dangerous products from the market, and demonstrating the efficacy, safety, and benefits of particular products.

CAM product regulation matters to an industry that seeks legitimacy and broader mainstream acceptance. Rather than stymieing the progress of legislation for the regulation of CAM products, the industry stands to make significant gains from legislation which supports its products through a cost-effective, risk-based proposal. If the endless claims of the industry that CAM products are safe, effective, and high quality are true, then regulation in line with the proposal in the CAM Products Bill will provide a simple and cheap way to gain high-tier approval for their CAM products under a light-touch risk-based scheme, inspiring consumer confidence, and providing substantial opportunities for the global potential of NZ CAM products.

The [Natural Health and Supplementary Products Bill] is regulatory overkill …
[and] is a solution looking for a problem.[1147]

[1147] Peters, above n 577.

Appendices

Appendix 1: Survey 1 University of Canterbury Human Ethics Committee Approval 'Human Perceptions on Dietary Supplements'

Approval from the University of Canterbury Human Ethics Committee follows for Survey 1; initially entitled 'Human Perceptions on Dietary Supplements', but known herein as 'Public Perceptions on Dietary Supplements: A Pilot Study'.

UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

HUMAN ETHICS COMMITTEE

Secretary, Rebecca Robinson
Telephone: +64 03 364 2987, Extn 45588
Email: human-ethics@canterbury.ac.nz

Ref: HEC 2016/37/LR

5 August 2016

Peter Harris
School of Law
UNIVERSITY OF CANTERBURY

Dear Peter

Thank you for submitting your low risk application to the Human Ethics Committee for the research proposal titled "Human Perceptions on Dietary Supplements".

I am pleased to advise that the application has been reviewed and approved.

Please note that this approval is subject to the incorporation of the amendments you have provided in your email of 2nd August 2016.

With best wishes for your project.

Yours sincerely

pp. R. Robinson

Jane Maidment
Chair, Human Ethics Committee

Appendix 2: Public Perceptions on Dietary Supplements: A Pilot Study

What follows is Survey 1: 'Public Perceptions on CAM Products: A Pilot Study' reproduced in its entirety. As noted in Chapter 9, this survey was conducted entirely online, which meant the format and rules associated with skipping questions where a negative answer was given, or selecting three of the six possible products to show each participant are not noted on the following version. Nevertheless, where these were vital to the study, they are noted in Chapter 9, and otherwise they should be presumed immaterial. As is normal in online surveys, a circular check icon is indicative of only one response being able to be selected, whereas a square check icon is indicative of multiple responses being able to be selected. The images reproduced here are used for the purposes of research and study.

Block 4

Q45.

School of Law & Department of Chemistry
Email: peter.harris@pg.canterbury.ac.nz
Phone Number: +64 27 257 6055
5 September 2016

UC UNIVERSITY OF CANTERBURY
Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

Public Perceptions on Dietary Supplements

Information Sheet for Participants
I am currently conducting research into the regulation of dietary supplements and natural health products for a Master of Laws. In this particular survey, I am looking at the effect of advertising and labeling on people's perceptions of dietary supplements, and consequently how this aligns with the legislation on the subject.

If you choose to take part in this study, your involvement in this project will be solely insofar as completing the following survey, which should take approximately 15 minutes. The survey involves answering some multi-choice questions, and some short answer questions.

There is no further follow-up to this survey.

We do not envisage any risks or harms arising from the course of the survey.

Participation is voluntary and you have the right to withdraw at any stage without penalty. You may ask for your raw data to be returned to you or destroyed at any point. If you withdraw, I will remove information relating to you.

The results of the project may be published, but you may be assured of the complete confidentiality of data gathered in this investigation: your identity will not be made public without your prior consent. To ensure anonymity and confidentiality, no personal information will be collected about you in the course of the survey. If you choose to enter the prize-draw at the end of the survey, your e-mail address will be separated from the responses in the survey and anonymised. It will only be used to contact you in the event that you win a prize in the random prize draw at the end of the survey. The raw survey data will only be accessible to the researcher and supervisors, either of which may be contacted as below. Survey data shall be securely stored in an encrypted, password protected format for five years as required for a Master's Thesis by the University of Canterbury, and shall then be destroyed. A thesis is a public document and will be available through the UC Library.

The project is being carried out as part of a Master of Laws by Thesis by Peter Harris, under the supervision of Dr Debra Wilson and Professor Ian Shaw, who can be contacted at either debra.wilson@canterbury.ac.nz or ian.shaw@canterbury.ac.nz. They will be pleased to discuss any concerns you may have about participation in the project.

This project has been reviewed and approved by the University of Canterbury Human Ethics Committee, and participants should address any complaints to The Chair, Human Ethics Committee, University of Canterbury, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz).

By choosing to continue, you are agreeing that you consent to participate in this survey and understand what is required of you. You are aware that participation is voluntary and you may withdraw at any time without penalty. You also acknowledge that while the survey is completely anonymous, the results will be publically available. Finally, you understand that you can contact the researcher, supervisors or Human Ethics Committee at any stage for further information or to express concerns or complain.

Peter Harris

Intro: Demographics & common habits

Q1. How old are you?

- ○ Under 18
- ○ 18 - 24
- ○ 25 - 34
- ○ 35 - 44
- ○ 45 - 54
- ○ 55 - 64
- ○ 65 - 74
- ○ 75 - 84
- ○ 85 or older

Q2. What gender do you identify with?

- ○ Male
- ○ Female
- ○ Prefer not to say
- ○ Other

Q3. What is your ethnicity?

- ○ New Zealand European/Pākehā
- ○ Māori
- ○ Pacific Islander
- ○ Asian
- ○ European
- ○ Prefer not to say
- ○ Other

Q4. What is your primary occupation?
(In the event of multiple options applying, please select the occupation which consumes the majority of your time).

- ○ Employed full time (more than 20 hours per week)
- ○ Employed part time (20 hours or less per week)
- ○ Unemployed
- ○ Retired
- ○ Student
- ○ Prefer not to say
- ○ Other

Q5. What is the highest level of education you currently hold?

- ○ Less than high school
- ○ High school graduate
- ○ Diploma, certificate or apprenticeship
- ○ Undergraduate tertiary qualification
- ○ Postgraduate qualification (other than doctorate)
- ○ Doctorate
- ○ Other

Q6. What is your annual income?

- ○ Less than $10,000
- ○ $10,000 - $19,999
- ○ $20,000 - $29,999
- ○ $30,000 - $39,999
- ○ $40,000 - $49,999
- ○ $50,000 - $59,999
- ○ $60,000 - $69,999
- ○ $70,000 - $79,999
- ○ $80,000 - $89,999
- ○ $90,000 - $99,999
- ○ $100,000 - $149,999
- ○ More than $150,000

Q46. How old are you?

- ○ Under 18
- ○ 18 - 24
- ○ 25 - 34
- ○ 35 - 44
- ○ 45 - 54
- ○ 55 - 64
- ○ 65 - 74
- ○ 75 - 84
- ○ 85 or older

Q47. What gender do you identify with?

- ○ Male
- ○ Female
- ○ Prefer not to say
- ○ Other

Q48. What is your ethnicity?

- ○ New Zealand European/Pākehā
- ○ Māori
- ○ Pacific Islander
- ○ Asian
- ○ European
- ○ Prefer not to say

- ○ Other

Q49. What is your primary occupation?
(In the event of multiple options applying, please select the occupation which consumes the majority of your time).

- ○ Employed full time (more than 20 hours per week)
- ○ Employed part time (20 hours or less per week)
- ○ Unemployed
- ○ Retired
- ○ Student
- ○ Prefer not to say
- ○ Other

Q50. What is the highest level of education you currently hold?

- ○ Less than high school
- ○ High school graduate
- ○ Diploma, certificate or apprenticeship
- ○ Undergraduate tertiary qualification
- ○ Postgraduate qualification (other than doctorate)
- ○ Doctorate
- ○ Other

Q51. What is your annual income?

- ○ Less than $10,000
- ○ $10,000 - $19,999
- ○ $20,000 - $29,999
- ○ $30,000 - $39,999
- ○ $40,000 - $49,999
- ○ $50,000 - $59,999
- ○ $60,000 - $69,999
- ○ $70,000 - $79,999
- ○ $80,000 - $89,999
- ○ $90,000 - $99,999
- ○ $100,000 - $149,999
- ○ More than $150,000

Q7. In the event of minor illness, what do you normally do?
(A minor illness is considered any short-lived condition which does not substantially prevent you carrying out your normal activities e.g. allergies, colds, aches and pains, skin conditions etc.)

- ○ See a Doctor
- ○ See a Natural Health or Alternative Practitioner
- ○ Self-medicate
- ○ Do nothing
- ○ Other

Q8. If you want to increase your immunity or your general health and well-being, what would you normally do?

- ○ See a Doctor
- ○ See a Natural Health or Alternative Practitioner
- ○ Self-medicate
- ○ Do nothing
- ○ Other

Q9. How often do you take non-prescribed medicines?

- ○ Daily
- ○ Weekly
- ○ 2-3 times per month
- ○ 1-2 times per month
- ○ 1-2 times per 6 months
- ○ 1-2 times per year

- Less Frequently
- Never

Q10. How often do you take dietary supplements or natural health products?

- Daily
- Weekly
- 2-3 times per month
- 1-2 times per month
- 1-2 times per 6 months
- 1-2 times per year
- Less Frequently
- Never

Part 1: Classification & Identification of foods, medicines & CAM products

Q11. How do you define a food?

Q12. How do you define a medicine?

Q13. How do you define a dietary supplement?

Q14. How do you tell the difference between a food, a dietary supplement and a medicine?

Q15.
If you were to purchase food, how would you identify that it is a food?

- Familiarity/brand recognition
- Appearance (shape & size)
- Labelling or packaging
- Other
- Place of purchase or location within the shop (e.g. food aisle)

Q16.
If you were to purchase medicine, how would you identify that it is a medicine?

- Familiarity/brand recognition
- Appearance (shape & size)
- Labelling or packaging
- Other
- Place of purchase or location within the shop (e.g. food aisle)

Q17.
If you were to purchase a dietary supplement, how would you identify that it is a dietary supplement?

- Familiarity/brand recognition
- Appearance (shape & size)
- Labelling or packaging
- Other
- Place of purchase or location within the shop (e.g. food aisle)

Part 2: The affect of labeling & therapeutic claims

Q18. The following page will contain an image of a dietary supplement or medicine acquired in New Zealand.
You will have 15 seconds to review the product label, as if you were considering purchasing it. After 15 seconds, the screen will automatically go to a series of questions on the product. The questions merely seek to gather your first impressions from the label.

This will be repeated with 3 different products, and the same questions.
Please click through when you're ready.

Q19. Pro ibssupport

Q20. You have 15 seconds to review this product label as if you were considering purchasing it. This screen will automatically go to a series of questions on the product after 15 seconds.

Q21. You have 15 seconds to review this product label as if you were considering purchasing it. This screen will automatically go to a series of questions on the product after 15 seconds.

Q22. You have 15 seconds to review this product label as if you were considering purchasing it. This screen will automatically go to a series of questions on the product after 15 seconds.

Q23. You have 15 seconds to review this product label as if you were considering purchasing it. This screen will automatically go to a series of questions on the product after 15 seconds.

Q24. You have 15 seconds to review this product label as if you were considering purchasing it. This screen will automatically go to a series of questions on the product after 15 seconds.

These page timer metrics will not be displayed to the recipient.

First Click: *0 seconds*

Last Click: *0 seconds*

Page Submit: *0 seconds*

Click Count: *0 clicks*

Q27. What do you think the benefits of taking this product would be?

Q28. Do you think that this product is a food, a medicine or a dietary supplement?

- ○ Food
- ○ Medicine
- ○ Dietary Supplement
- ○ Other (please note)

Q26. Why would you purchase this product instead of a medicine?

Q29. In comparison to a medicine:

	Much better	Somewhat better	About the same	Somewhat worse	Much worse
How effective is treatment by this product, compared to a medicine for the same illness?	○	○	○	○	○
How does this product's trustworthiness rate compared to a medicine?	○	○	○	○	○

Q30. How effective will this product be at the following:

	Extremely effective	Very effective	Moderately effective	Slightly effective	Not effective at all
Altering the shape, size or weight of your body?	○	○	○	○	○
Curing or alleviating a disease or ailment?	○	○	○	○	○
Preventing you from catching a disease or ailment?	○	○	○	○	○
Interfering with your body's normal processes?	○	○	○	○	○

Part 3: The impact of the environment of sale & factors which inform purchasing

Q31. What connotations do the following terms have to you?

	Safe			Effective			Could have side-effects (known or unknown)		Necessary to a healthy life/diet		Any other connotations or thoughts?
	Yes	No	Sometimes	Yes	No	Sometimes	Yes	No	Yes	No	(Please write below)
"Natural Medicines"	○	○	○	○	○	○	○	○	○	○	
"Herbal Remedies"	○	○	○	○	○	○	○	○	○	○	
"Homeopathic Remedies"	○	○	○	○	○	○	○	○	○	○	
"Vitamin & Mineral Supplements"	○	○	○	○	○	○	○	○	○	○	
"Medicines"	○	○	○	○	○	○	○	○	○	○	
"Natural Health Products"	○	○	○	○	○	○	○	○	○	○	
"Dietary Supplements"	○	○	○	○	○	○	○	○	○	○	

Q32. Have you ever purchased dietary supplements?

- ○ Yes
- ○ No

Q33. What factors do you/would you take into account when purchasing dietary supplements?

- ☐ Advice from friends/colleagues
- ☐ Advice from store-person
- ☐ Advice from natural health practitioner
- ☐ Advice from doctor
- ☐ Price
- ☐ Label
- ☐ Environment of sale
- ☐ Product knowledge
- ☐ Name recognition
- ☐ Suitability to cure ailment
- ☐ Product safety
- ☐ Scientific evidence
- ☐ Traditional evidence
- ☐ Other (please note)

Q34. How likely are you to buy dietary supplements from the following places?
Rank from 1 (very likely) - 7 (very unlikely)

- Health Store
- Overseas Online Store
- Pharmacy
- Supermarket
- Natural Health Practitioner
- New Zealand Online Store
- Doctor

Q35. If a medicine and a dietary supplement intended for the treatment of the same illness cost the same, which would you buy?

- ○ Medicine
- ○ Dietary Supplement

Q36. Why would you preferentially buy the ${q://QID24/ChoiceGroup/SelectedChoices} ?

Q37. What information would you like to see on the label or sale environment of dietary supplements? (optional)

Q38. Any other comments? (optional)

Appendix 3: Survey 2 University of Canterbury Human Ethics Committee Approval 'Packaging of Complementary and Alternative Medicines in New Zealand: A Representative Survey'

Approval from the University of Canterbury Human Ethics Committee follows for Survey 2; entitled 'Packaging of Complementary and Alternative Medicines in New Zealand: A Representative Survey'.

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Te Whare Wānanga o Waitaha
CHRISTCHURCH NEW ZEALAND

HUMAN ETHICS COMMITTEE

Secretary, Rebecca Robinson
Telephone: +64 03 369 4588, Extn 94588
Email: human-ethics@canterbury.ac.nz

Ref: HEC 2016/68/LR

9 December 2016

Peter Harris
School of Law
UNIVERSITY OF CANTERBURY

Dear Peter

Thank you for submitting your low risk application to the Human Ethics Committee for the research proposal titled "Packaging of Complementary and Alternative Medicines in New Zealand: A Representative Survey".

I am pleased to advise that the application has been reviewed and approved.

The Committee suggest that for the questionnaire you use New Zealand Census formatting to elicit ethnicity data.

With best wishes for your project.

Yours sincerely

pp. R. Robinson

Jane Maidment
Chair, Human Ethics Committee

Appendix 4: Packaging of Complementary and Alternative Medicines in New Zealand: A Representative Survey

What follows is Survey 2: 'Packaging of Complementary & Alternative Medicines in New Zealand: A representative study' reproduced in its entirety. As noted at Chapter 10, this survey was conducted through both physical distributions via the post, and online distributions through the Qualtrics software. For the purposes of reproducibility, the postal version follows, as this contains explicit directions for questions like 10 & 11, where otherwise participants would not have been privy to the rules used which excluded display of the question depending on the answer to the preceding question. Both version one and version two of this survey are included in their entirety to demonstrate the overall similarity, barring questions 13-18 where the packaging and labelling were altered between versions. See Chapter 10 for a detailed discussion on these different versions.

«Unique_ID_No»

School of Law

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CHRISTCHURCH NEW ZEALAND

«Title» «Forenames» «Surname»
«Address_Line_1»
«Address_Line_2»
«Address_Line_3»
«Address_Line_4»
«Address_Line_5»

Dear «Title» «Surname»,

I am conducting a survey of New Zealanders for research on dietary supplements and medicines, and how they are marketed. As part of this, would you mind taking a few moments to complete this survey?

A brief information sheet and the survey are included in this letter, as well as a postage paid envelope for you to return the survey. Alternatively, if you would prefer, the survey may be conducted online at «Simplified_Web_Address». The survey closes on Friday 31 March 2017, so I would be grateful if you could return your completed survey before this date. This is a follow-up letter to that sent in January in the hope that you may now have time to complete this survey.

This survey should take no more than 5-10 minutes for you to complete, and I would be very appreciative of your assistance.

Permission was received from the Electoral Commission and the University of Canterbury Human Ethics Committee to use the New Zealand Electoral Roll for the purposes of human health research for this survey. Your contact details were randomly selected from the Electoral Roll to participate in this survey.

If you have any further questions, please see the information sheet on the following page which contains further details on this survey, as well as my contact information and that of the supervisors of this research. The project has been reviewed and approved by the University of Canterbury Human Ethics Committee.

Thank you for your participation,

Peter Harris

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Peter Harris
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CHRISTCHURCH NEW ZEALAND

Packaging of Complementary and Alternative Medicines in New Zealand: A representative survey

Information Sheet for Participants

I am currently conducting research into the packaging of complementary and alternative medicine products as part of a study towards a Master of Laws. In this particular survey, I am looking at the effect of packaging and labelling on how people identify dietary supplements and medicines, and consequently how this aligns with the legislation on the subject.

If you choose to take part in this study, your involvement in this project will consist of completing the following survey, which should take approximately 10 minutes. The survey involves answering a series of short, multi-choice questions. I do not envisage any risks or harms to you arising from the course of the survey.

Participation is voluntary and you have the right to withdraw at any stage without penalty. You may ask for your raw data to be returned to you or destroyed at any point until the close of the survey. If you withdraw, I will remove information relating to you. However, once analysis of raw data starts after the survey closes, it will become increasingly difficult to remove the influence of your data on the results.

The results of the project may be published, but you may be assured of the complete confidentiality of data gathered in this investigation: your identity will not be made public without your prior consent. To ensure anonymity and confidentiality, no identifying information will be collected about you in the course of the survey. The raw survey data will only be accessible to the researcher and supervisors, either of which may be contacted as below. Survey data shall be securely stored in an encrypted, password protected format for five years as required for a Master's Thesis by the University of Canterbury, and shall then be destroyed. A thesis is a public document and will be available through the UC Library.

The project is being carried out as part of a Master of Laws by Thesis by Peter Harris, under the supervision of Dr Debra Wilson and Professor Ian Shaw, who can be contacted at either debra.wilson@canterbury.ac.nz or ian.shaw@canterbury.ac.nz. They will be pleased to discuss any concerns you may have about participation in the project.

This project has been reviewed and approved by the University of Canterbury Human Ethics Committee, and participants should address any complaints to The Chair, Human Ethics Committee, University of Canterbury, Private Bag 4800, Christchurch (human-ethics@canterbury.ac.nz).

By choosing to continue with the survey, you are agreeing that you consent to participate in this survey and understand what is required of you. You are aware that participation is voluntary and you may withdraw at any time without penalty. You also acknowledge that while the survey is completely anonymous, the results will be publically available. Finally, you understand that you can contact the researcher, supervisors or Human Ethics Committee at any stage for further information or to express concerns or complaints.

Peter Harris

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CHRISTCHURCH NEW ZEALAND

Packaging of Complementary and Alternative Medicines in New Zealand: A representative survey

Q1 How old are you?

- ❍ 18 - 24
- ❍ 25 - 34
- ❍ 35 - 44
- ❍ 45 - 54
- ❍ 55 - 64
- ❍ 65 - 74
- ❍ 75 - 84
- ❍ 85 or older

Q2 What gender are you?

- ❍ Male
- ❍ Female
- ❍ Prefer not to say
- ❍ Other (please explain) _____

Q3 Which ethnic group do you belong to? (Mark the option or options which apply to you)

- ❑ New Zealand European
- ❑ Māori
- ❑ Samoan
- ❑ Cook Islands Māori
- ❑ Tongan
- ❑ Niuean
- ❑ Chinese
- ❑ Indian
- ❑ Prefer not to say
- ❑ Other (please state: e.g. Dutch, Japanese, Tokelauan) _____

Q4 What is your employment status? (In the event of multiple options applying, please select the one which consumes the majority of your time)

- ❍ Employed full time (more than 20 hours per week)
- ❍ Employed part time (20 hours or less per week)
- ❍ Unemployed
- ❍ Retired
- ❍ Student
- ❍ Prefer not to say
- ❍ Other (please explain) _____

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Q5 What is your highest level of education?

- ❍ Less than high school
- ❍ High school graduate
- ❍ Diploma, certificate or apprenticeship
- ❍ Undergraduate tertiary qualification
- ❍ Postgraduate qualification (other than doctorate)
- ❍ Doctorate
- ❍ Prefer not to say
- ❍ Other (please explain) _____

Q6 What is your annual income?

- ❍ Less than $10,000
- ❍ $10,000 - $19,999
- ❍ $20,000 - $29,999
- ❍ $30,000 - $39,999
- ❍ $40,000 - $49,999
- ❍ $50,000 - $59,999
- ❍ $60,000 - $69,999
- ❍ $70,000 - $79,999
- ❍ $80,000 - $89,999
- ❍ $90,000 - $99,999
- ❍ $100,000 - $149,999
- ❍ More than $150,000
- ❍ Prefer not to say

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Definitions

Medicine: For the purposes of this survey, a medicine is defined as a drug or other preparation for the treatment or prevention of disease.

Dietary Supplement: For the purposes of this survey, a dietary supplement is a product which contains herbs, minerals, vitamins, natural or supplementary nutritional oils or any other product generally considered a complementary or alternative medicine product or a natural health product. Such a product is not a medicine.

Q7 Have you ever bought a dietary supplement?

- ❍ Yes
- ❍ No

Q8 Have you ever taken a dietary supplement?

- ❍ Yes *(go to Q8a)*
- ❍ No *(go to Q9)*

If you answered 'Yes' to Question 8;

Q8a How frequently do you take dietary supplements?

- ❍ Daily
- ❍ Weekly
- ❍ 2-3 times per month
- ❍ 1-2 times per month
- ❍ 1-2 times per 6 months
- ❍ 1-2 times per year
- ❍ Less frequently

S1

The following questions show 6 images of product packaging. Some of these packages contain labels which have a statement about the purpose or effect of the product. Please select the answer you believe **best fits** the product, based off your first impressions.

Q9

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other_____

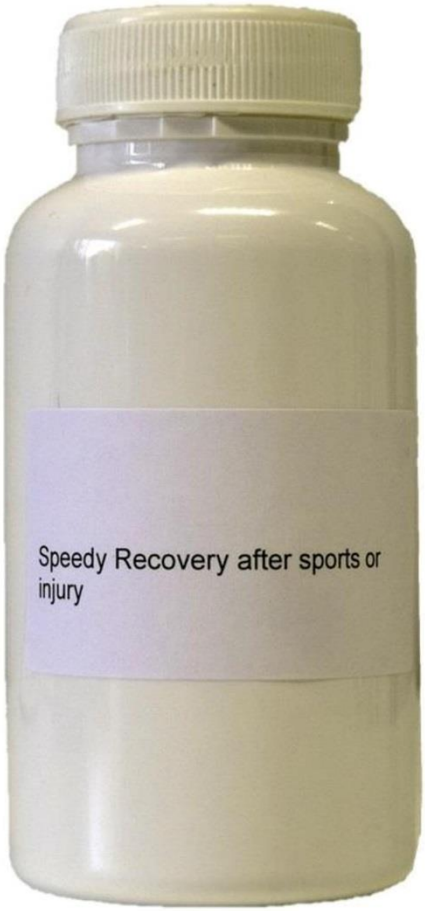
Q10

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other _____

Q11

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other

_____



Q12

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other

_____

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Q13

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other_____

Q14

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other _____

Q15 Any other comments or observations on the labeling, packaging or therapeutic claims on medicines and/or dietary supplements? (Optional)

Thank you for completing this survey.
Please enclose the completed survey in the postage paid envelope and return at your earliest convenience.

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Peter Harris

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Packaging of Complementary and Alternative Medicines in New Zealand: A representative survey

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- ❍ Female
- ❍ Prefer not to say
- ❍ Other (please explain) _____

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- ❑ Cook Islands Māori
- ❑ Tongan
- ❑ Niuean
- ❑ Chinese
- ❑ Indian
- ❑ Prefer not to say
- ❑ Other (please state: e.g. Dutch, Japanese, Tokelauan) _____

Q4 What is your employment status? (In the event of multiple options applying, please select the one which consumes the majority of your time)

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- ❍ Retired
- ❍ Student
- ❍ Prefer not to say
- ❍ Other (please explain) _____

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Q5 What is your highest level of education?

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- ❍ High school graduate
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- ❍ Undergraduate tertiary qualification
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- ❍ Doctorate
- ❍ Prefer not to say
- ❍ Other (please explain) _____

Q6 What is your annual income?

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- ❍ $20,000 - $29,999
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- ❍ No

Q8 Have you ever taken a dietary supplement?

- ❍ Yes *(go to Q8a)*
- ❍ No *(go to Q9)*

If you answered 'Yes' to Question 8;

Q8a How frequently do you take dietary supplements?

- ❍ Daily
- ❍ Weekly
- ❍ 2-3 times per month
- ❍ 1-2 times per month
- ❍ 1-2 times per 6 months
- ❍ 1-2 times per year
- ❍ Less frequently

S2

The following questions show 6 images of product packaging. Some of these packages contain labels which have a statement about the purpose or effect of the product. Please select the answer you believe **best fits** the product, based off your first impressions.

Q13

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other_____

Q14

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other_____

Q15

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other

_____

Q16

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other

_____

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Q17

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other

_____

Q18

- ❍ Medicine
- ❍ Dietary Supplement
- ❍ Other

_____

Q19 Any other comments or observations on the labeling, packaging or therapeutic claims on medicines and/or dietary supplements? (Optional)

Thank you for completing this survey.
Please enclose the completed survey in the postage paid envelope and return at your earliest convenience.

Appendix 5: The Complementary and Alternative Medicinal Products Bill

Complementary and Alternative Medicinal Products Bill

Part 1

Preliminary provisions

1 Title

This Act is the Complementary and Alternative Medicinal Products Act 2017.

2 Overview

(1) This Act replaces the Dietary Supplements Regulations 1985.

(2) This Part contains preliminary provisions that—

(a) state the purpose of this Act; and

(b) state the principles of this Act; and

(c) define certain terms used in this Act.

(3) Part 2 relates to the risk-based approach to regulation of complementary and alternative medicinal products. In particular, it includes provisions that—

(a) provide for the classification of complementary and alternative medicinal products into 3 tiers based on, among other things, the level of risk that they pose to public health; and

(b) establish a black-list of compounds or ingredients that are prohibited from being complementary and alternative medicinal products, or being components of complementary and alternative medicinal products; and

(c) establish a pathway for dietary supplements regulated under the Dietary Supplements Regulations 1985 to come within the 3 risk-based tiers for the duration of the introductory period of this Act, or until the manufacturer has sought reclassification of the complementary and alternative medicinal product.

(4) Part 3 contains provisions relating to the administration of the Act. In particular, it includes provisions that—

(a) provide for the structure and composition of the regulatory authority and subcommittees under the Act; and

(b) outline the duties and functions of the regulatory authority and subcommittees under this Act; and

(c) establish a framework for recognition of international authorities and resources in accordance with the principles and risk-based approach in this Act; and

(d) empowering the regulatory authority to make regulations for the functioning and administration of this Act.

(5) Part 4 contains provisions relating to the enforcement under this Act, and includes provisions that—

(a) establish offences under this Act; and

(b) set penalties for offences under this Act; and

(c) provide additional order which the regulator may make for enforcement under this Act; and

(d) deal with the court's powers to make additional orders for effective enforcement.

(6) Schedule 1 sets out the black-list of prohibited products or ingredients as required under this Act.

(7) Schedule 2 sets out approved international regulators as approved under this Act.

(8) Schedule 3 sets out approved published materials as approved under this Act.

(9) This section is intended as a guide only.[1148]

3 Purpose

The purpose of this Act is to—

(a) restate and reform the law relating to the sale, marketing, advertising, and trade of complementary and alternative medicinal products; and

(b) achieve safety and quality in complementary and alternative medicinal products; and

(c) regulate complementary and alternative medicinal products in a manner commensurate with the risk of these products, by providing for a risk-based approach that—

(i) minimises and manages the risks to public health; and

(ii) ensures any claims of efficacy are supported by sound scientific evidence; and

(d) require persons who trade in complementary and alternative medicinal products to take responsibility for the safety and suitability of those products.[1149]

4 Principles

This Act is based on the following principles:

(a) that the regulation of complementary and alternative medicinal products is managed by a risk-based approach; and

(b) that the regulation, classification, sale, trade, marketing, advertising, decision making and any other matters under this Act are all supported by sound scientific evidence, unless otherwise stipulated in the risk-based approach; and

[1148] Compare: Food Act 2014, s3.

[1149] Compare: Food Act 2014, s4; Natural Health and Supplementary Products Bill 2011 (324-2), cl3.

(c) that the regulation of complementary and alternative medicinal products under this Act favour a flexible approach, where products are reasonably judged on their own merits.[1150]

5 Interpretation

In this Act, unless the context otherwise requires, —

black-list means the register of prohibited products or ingredients, listed in Schedule 1 and declared by the Regulatory Authority under section 10 to be a prohibited substance on the basis of a risk assessment

complementary and alternative medicinal product has the meaning given to it by section 6

dietary supplement is a sub-group of complementary and alternative medicinal products that—

(a) is intended to be ingested orally; and

(b) is intended to supplement the amount of amino acid, edible substance, herb, mineral, synthetic nutrient, or vitamin normally derived from food products[1151]

efficacy claims are statements on the positive benefits or effects of complementary and alternative medicinal products that—

(e) are prohibited for tier 3 products; but

(f) are permitted for tier 2 products where they—

(i) are supported by scientific evidence; and

(ii) are on prophylactic uses for complementary and alternative medicinal products, including, but not limited to dietary supplementation and nutritional support; and

(g) are permitted for tier 1 products where they—

(i) are supported by scientific evidence; and

(ii) are on prophylactic uses for complementary and alternative medicinal products, including, but not limited to dietary supplementation and nutritional support; or

(iii) are for relief of mild, or low-grade medical conditions; or

(iv) are for symptomatic relief from the effects of mild, or low-grade medical conditions; but

(h) do not include statements that—

(i) claim to cure any medical condition; or

[1150] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl4.

[1151] Compare: Dietary Supplements Regulations 1985, reg2A; Natural Health and Supplementary Products Bill 2011 (324-2), cl5 'dietary supplement'.

(ii) claim to treat any medical condition; or

(iii) make any reference to acute illness, chronic illness, severe illness, cancer, or any other serious curable, manageable, or treatable medical condition; or

(iv) relate to children, or childhood illnesses in any way

food products—

(c) means any product which has the appearance of food products or drink as they are ordinarily understood; and

(d) either—

(i) is primarily intended for human consumption as food products or drink; or

(ii) is primarily used as an ingredient in food products or drink for human consumption; and

(c) includes—

(i) formulated supplementary sports food as defined by standard 2.9.4 Australia New Zealand Food Standards Code 2002; and

(ii) supplemented food as defined by the New Zealand Food (Supplemented Food) Standard 2016[1152]

healthcare advisory statement is a statement which notes—

(b) if side effects occur, please consult your doctor or pharmacist, and remember to always check with your healthcare professional before mixing medicines and CAM products[1153]

herbal medicine or herbal remedy is a sub-group of complementary and alternative medicinal products that—

(c) includes—

(i) any substance produced by subjecting a plant to drying crushing , or any other similar process; or

(ii) a mixture comprising 2 or more such substances only; or

(iii) a mixture comprising 1 or more such substances with water or ethyl alcohol or any inert substance; and

(d) is not a medicine[1154]

homeopathy is a sub-group of complementary and alternative medicinal products in which the active ingredient to be administered is in a concentration of not more than 10 parts per million.

[1152] Compare: Food Act 2014, s9; Consumer Guarantees Act 1993, s2; Natural Health and Supplementary Products Bill 2011 (324-2), cl6(3).

[1153] Compare: Medicines Regulations 1984, reg13.

[1154] Compare: Medicines Act 1981, s2 'herbal remedy'.

Minister means the Minister of the Crown who, under the authority of the Prime Minister, is responsible for the administration of the Act

medicine

(c) is a product that—

(i) is used for a therapeutic purpose within the meaning of section 4 of the Medicines Act 1981; and

(ii) the Minister has, under section 20 or 23 of that Act, given consent to its distribution; or

(iii) the Minister is, under section 20(7) of that Act, deemed to have given consent to its distribution; or

(iv) the Director-General, has under section 24 of that Act, given consent to its distribution;

(d) includes—

(i) any related product that the Minister has, under section 20 and 96 of the Medicines Act 1981, given consent to its distribution; or

(ii) any medical device that is the subject of a declaration under regulation 6 of the Medicines (Database of Medical Devices) Regulations 2003[1155]

primary display means the part of a label that is most likely to be displayed, presented, shown, or examined, under ordinary or customary conditions of display for retail sale; and, in the case of cylindrical packaging or labelling, the width of the primary display shall not exceed one-third of the circumference of the package[1156]

rongoā Māori means the practice of Māori traditional medicine and is not regulated by this Act where it comes within the scope of complementary and alternative medicine practices at section 6(2); but where traditional Māori remedies are produced on a commercial scale for sale or supply outside the practice of rongoā Māori, this Act will apply as if they are a traditional medicine products

scientific evidence

(b) includes—

(i) randomised, blind, placebo controlled studies; or

(ii) meta-analyses or systematic reviews; or

(iii) reputable scientific texts; or

(iv) sound, peer reviewed research; or

(v) material in reputable peer-reviewed scientific journals; or

[1155] Compare: Medicines Act 1981, s3(1); Natural Health and Supplementary Products Bill 2011 (324-2), cl6(2).
[1156] Compare: Dietary Supplements Regulations 1985, reg2 'principal display panel' and reg8; Medicines Act 1981, reg2 'principal display panel'.

(vi) monographs or similar materials from approved international regulators, as listed in Schedules 2 and 3; or

(vii) repeatable experiments; or

(viii) chemical or biological structure modelling; or

(ix) chemical structure-activity modelling; or

(x) verifiable quantitative research; or

(xi) any combination of the above requirements; or

(xii) other material deemed to be sound scientific evidence by the regulatory authority[1157]

traditional evidence is evidence of a longstanding history of use of traditional medicine products, commonly sourced from approved published materials listed in Schedule 3[1158]

traditional medicine products is a sub-group of complementary and alternative medicinal products that—

(c) includes—

(i) any traditional or indigenous medicine which has a longstanding history of use; but

(d) does not include—

(i) rongoā Māori

6 Meaning of complementary and alternative medicinal product

(1) In this Act, subject to any specific definition provided for use in another section, **complementary and alternative medicinal product—**

(a) is any product that—

(i) is intended for human use; and

(ii) shows scientific evidence or traditional evidence for its safety; and

(iii) has a risk commensurate with the benefit of the product; and

(iv) is approved for sale and classified by the complementary and alternative products regulatory authority; and

(b) includes—

(i) dietary supplements; and

(ii) herbal medicine or herbal remedies; and

[1157] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl5 'scientific evidence'.
[1158] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl5 'traditional evidence'.

(iii) homeopathy; and

(iv) traditional medicine products products; but

(c) does not include—

(i) any product or ingredient included on the black-list; and

(ii) complementary and alternative medicine practices, or specialist products formulated for an individual patient and dispensed in the course of the practice; and

(iii) any food products, or product presented as a food product; and

(iv) any medicine, or product presented as a medicine; and

(v) any product administered by injection, parenteral infusion, application to the eye, or application to the ear of any human.

(2) In this section, **complementary and alternative medicine practices** means any practice which is not a part of standard medical healthcare in New Zealand.

7 Treaty of Waitangi (Te Tiriti o Waitangi)

In achieving the purpose of this Act, all persons exercising functions and powers under it shall take into account the principles of the Treaty of Waitangi.[1159]

Part 2

Risk-based Approach

8 Overview of this Part

(1) This Part contains provisions relating to the risk-based approach, which is the main means under this Act for ensuring complementary and alternative medicinal products are safe, supported by evidence, and where relevant, effective.

(2) This Part—

(a) classifies complementary and alternative medicinal products into 3 risk tiers based on, among other things, the level of risk that they pose to public health when balanced with their benefit; and

(b) outlines general requirements for complementary and alternative medicinal products in each of the 3 tiers under this Act; and

(c) outlines labelling requirements for complementary and alternative medicinal products in each of the 3 tiers under this Act; and

(d) outlines the required evidence which manufacturers or importers must submit to the regulatory authority for the classification of a complementary and alternative medicinal product in each of the 3 tiers under this Act.

[1159] Compare: Resource Management Act 1991, s8; Environmental Protection Authority Act 2011, s4; State-Owned Enterprises Act 1986, s9.

(3) This Part also contains provisions that create the black-list.[1160]

	Tier 1 Top tier	**Tier 2** Middle tier	**Tier 3** Bottom tier
General	High benefit, low risk	High benefit, Moderate risk Moderate benefit, low risk	Low benefit, very low risk No benefit, very low risk
	Can make strong efficacy claims	Can make weak efficacy claims	Cannot make efficacy claims
	May be required to specify purpose	May be required to specify purpose	Cannot specify purpose
	No packaging restrictions	May be limit on amount of product per package	Products cannot be packaged in boxes
	Lowest annual licencing fees	Moderate annual licencing fees	High annual licencing fees
Labelling Requirements	Labelled with a (green dot) and 'Tier 1 CAM product' on primary display	Labelled with a (orange dot) and 'Tier 2 CAM product' on primary display	Labelled with a (red dot) and 'Tier 3 CAM product' or 'Tier 3 Homeopathic product' on primary display
	Must make healthcare advisory statement	Must make healthcare advisory statement. Must list side-effects	Must make healthcare advisory statement
	Must list all ingredients	Must list all ingredients	Must list all ingredients
Evidence Requirements for Classification	Must supply a copy of the label	Must supply a copy of the label	Must supply a copy of the label
	Must have scientific evidence on safety. Biochemical basis for mode of action and toxicological safety assessments likely required - traditional evidence is insufficient.	Must show sound evidence of safety – traditional evidence unlikely to be enough alone	Must show some evidence of safety – traditional evidence will suffice
	Must show biochemical mode of action, and provide sound scientific evidence for efficacy claims, e.g. monographs, peer reviewed research of clinical studies	Must hold scientific evidence for any efficacy claims. Monographs, peer reviewed research, or clinical studies all accepted. Theoretical basis may be acceptable.	No proof of efficacy required
	Must provide evidence of GMP, Quality Control and product testing	Must provide evidence of GMP & Quality Control plans	Must provide evidence of GMP & Quality Control plans
	Must provide evidence of structural similarity assessments	Must provide evidence of structural similarity assessments	No structural similarity assessment necessary

[1160] Compare: Food Act 2014, s20.

Examples	Iron products	Olive Leaf	- Arnica 6X Drops (Homeopathic) - Men's Multivitamins

Table 12.1: A Proposed Risk-based Approach for CAM Product Regulation

9 Classification of complementary and alternative medicinal product tiers for purpose of assigning applicable risk-based approaches

(1) The classification of complementary and alternative medicinal product tiers under this Part—

(a) is based on, among other things, the level of risk that their activities pose to public health in terms of the safety and suitability of complementary and alternative medicinal products; and

(b) is for the purpose of ensuring that the information presented to the public on the labelling, packaging and advertising of complementary and alternative medicinal products accords with the risk posed by the particular product; and

(c) is for the purpose of ensuring certainty amongst all stakeholders on the evidential requirements and effect of the classification of complementary and alternative medicinal products on the 3 risk-based tiers.

(2) Accordingly, the regulatory authority is responsible for the classification of individual products into 1 of the 3 risk-based tiers upon application by the manufacturer, importer, or other interested party, in accordance with the measures set out in subsection (3).

(3) The measures referred to in subsection (2) are as follows:

(a) complementary and alternative medicinal products that generally pose a high benefit and commensurately low risk are classified as Tier 1 products; and—

(i) must supply scientific evidence in support of the safety of the product and its effect; and

(ii) are subject to labelling and advertising regulations as appropriate to the individual product; and

(iii) must supply any other material reasonably required by the regulatory authority as stipulated in the regulations to this Act:

(b) complementary and alternative medicinal products that generally pose either a high benefit and commensurately moderate risk, or a moderate benefit and commensurately low risk are classified as Tier 2 products and—

(i) must supply scientific evidence, and where relevant, traditional evidence, in support of the safety of the product and its effect; and

(ii) are subject to labelling, packaging, and advertising regulations as appropriate to the individual product; and

(iii) must supply any other material reasonably required by the regulatory authority as stipulated in the regulations to this Act:

(c) complementary and alternative medicinal products that generally pose either a low benefit and commensurately very low risk, or no benefit and commensurately very low risk are classified as Tier 3 products and—

(i) must supply either scientific evidence, or traditional evidence, in support of the safety of the product; and

(ii) are subject to labelling, packaging, and advertising regulations as appropriate to the individual product; and

(iii) must supply any other material reasonably required by the regulatory authority as stipulated in the regulations to this Act.

(4) When applying for classification in 1 of the 3 risk-based tiers, the manufacturer, importer, or other interested party must pay a classification fee for the regulator's assessment of the complementary and alternative medicinal product;

(a) that—

(i) is a higher than average fee, for a product seeking Tier 1 classification; or

(ii) is an average fee, for a product seeking Tier 2 classification; or

(iii) is a lower than average fee, for a product seeking Tier 3 classification.

(5) Subsection (4) applies in the same way to products seeking reclassification.[1161]

10 Prohibited products or ingredients

(1) The Regulatory Authority may, on the recommendation of the Expert Advisory Committee, declare an ingredient or complementary and alternative medicinal product to be a prohibited ingredient or complementary and alternative medicine product, and require that product to be listed in Schedule 1.

(2) In tendering advice to the Minister under subsection (1) about an ingredient or complementary and alternative medicinal product to be listed in Schedule 1, the Regulatory Authority must provide the Minister with a report that sets out the following:

(a) information about the ingredient or product; and

(b) a risk-assessment of the ingredient or product drawn from scientific evidence; and

(c) advice as to whether, in the Authority's expert opinion, the known risks to public health of the ingredient or product fall within a level of risk that is acceptable in New Zealand; and

(d) any traditional evidence or published history of traditional use; and

(e) any other matter that the Authority considers relevant in the circumstances.

(3) A declaration made by the Minister under this section must be published on an Internet site maintained by or on behalf of the Authority.[1162]

[1161] Compare: Food Act 2014, s21.

[1162] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl21; Human Assisted Reproductive Technology Act 2004, ss6 and 8.

Part 3

Administration

11 Overview of this Part

(1) This Part contains provisions relating to the administration of the Act.

(2) This Part—

(a) provides a structure for the transition between the previous legislation governing complementary and alternative medicinal products and the risk-based approach in the current Act; and

(b) establishes the Complementary and Alternative Medicinal Products Regulatory Authority; and

(c) specifies the roles of the Regulatory Authority; and

(d) provides for a list of approved international regulatory authorities whose regulation of complementary and alternative medicinal products is able to be considered or employed in the regulation of complementary and alternative medicinal products under this Act; and

(e) provides for a list of approved materials which may be able to be considered or employed in the regulation of complementary and alternative medicinal products under this Act.[1163]

12 Overview of transitional provisions

(1) This section describes the general scheme and effect of the transitional provisions contained in this subpart. It is by way of explanation only and does not limit or affect the other provisions of this Act.

(2) The Dietary Supplements Regulations 1985 are repealed in this subpart.

(3) Sections in this subpart on preliminary registration of all complementary and alternative medicinal products come into force on the day after that date on which this Act receives the Royal assent.

(4) All complementary and alternative medicines have 1 year for preliminary registration.

(5) The transitional provisions in this subpart come into force a year and a day after the date on which this Act receives the Royal assent.

(6) All preliminarily registered complementary and alternative medicinal products will have a 5 year authorised period from the date in subsection (5) to make the transition from the Dietary Supplements Regulations to the new requirements of this Act.

(7) During that period, all preliminarily registered complementary and alternative medicinal products will be nominally classified as Tier 3 products, and subject to the annual licencing fees associated with this classification.

[1163] Compare: Food Act 2014, s20.

(8) Complementary and alternative medicinal products can apply for classification at any time from the day after the date on which this Act receives Royal assent.[1164]

13 Complementary and Alternative Medicinal Products Regulatory Authority

(1) This section establishes the Complementary and Alternative Medicinal Products Regulatory Authority (the Authority).

(2) The Authority is the Director-General of Health.

(3) The office of the Authority must be administered by the Ministry of Health.[1165]

14 Role of the Regulatory Authority

(1) The Regulatory Authority has the functions, duties, and powers given to it under this Act.

(2) The Regulatory Authority has a role in the complementary and alternative medicinal product regime that includes, without limitation,—

(a) engaging in post-market surveillance of any complementary and alternative medicinal product, including:

(i) monitoring compliance with the applicable requirements of this Act; and

(ii) conducting any testing on complementary and alternative medicinal products to verify their contents, safety, efficacy or veracity of their claims, as appropriate.

(b) co-ordinating the response to emergencies that may undermine the purpose of this Act; and

(c) implementing, managing, monitoring, and auditing the risk-based measures for the safety, suitability, and where appropriate, efficacy, of complementary and alternative medicinal products; and

(d) providing information to the complementary and alternative medicinal product industry and the public on matters relating to the safety, suitability, and where appropriate, efficacy, of complementary and alternative medicinal products; and

(e) establishing and maintaining the public registers; and

(f) developing standards and implementing those standards for the safety, suitability, and where appropriate, efficacy, or complementary and alternative medicinal products; and

(g) performing the function of a registration authority; and

(h) conducting, on application, reviews of certain decisions made by persons acting under its delegated authority; and

(i) monitoring and implementing the enforcement system under this Act and working collaboratively with other regulatory bodies; and

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[1164] Compare: Food Act 2014, s413.

[1165] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl8.

(j) prescribe fees and charges for the purposes of cost recovery, as stipulated in the regulations to the Act; and

(k) exempt persons from the application of this Act generally; and

(l) carrying out any functions that are incidental and related to, or consequential upon, the roles set out in paragraphs (a) to (k).[1166]

15 Complementary and Alternative Medicinal Products Expert Advisory Committee must be established

(1) The Authority must establish an expert advisory committee known as the Expert Advisory Committee on Complementary and Alternative Medicinal Products (Expert Advisory Committee).[1167]

16 Structure of the Expert Advisory Committee

(1) The Expert Advisory Committee—

(a) consists of not fewer than 8 and not more than 12 members; and

(b) may, subject to this Act and any directions that the Regulatory Authority gives by written notice to the committee, regulate its procedure in any manner that the committee thinks fit.

(2) Each meeting of the Expert Advisory Committee may be attended by the chairperson of the Māori Advisory Committee or a member of the Māori Advisory Committee nominated by the chairperson of the Expert Advisory Committee, but a person attending under this subsection is not a member of the Expert Advisory Committee.

(3) The Expert Advisory Committee must include—

(a) 1 or more members with expertise in complementary and alternative medicinal products and complementary and alternative medicinal products research; and

(b) 1 or more registered medical professionals; and

(c) 1 or more Ministry of Health representatives; and

(d) 1 or more members with the ability to articulate issues from a consumer perspective; and

(e) 1 or more toxicologist; and

(f) 1 or more members with expertise in relevant areas of the law; and

(g) 2 members with the ability to represent the interests of the complementary and alternative medicinal products industry, including, but not limited to;

(i) manufacturers; or

(ii) importers; or

(iii) industry bodies; or

[1166] Compare: Food Act 2014, ss17-19.

[1167] Compare: Human Assisted Reproductive Technology Act 2004, s32.

(iv) retailers.[1168]

17 Functions of the Expert Advisory Committee

(1) The Expert Advisory Committee has the following functions:

(a) to collaborate and refer decisions to the Māori Advisory Committee, and take the advice of the Māori Advisory Committee where appropriate on matters involving;

(i) Māori traditional knowledge; or

(ii) Māori traditional medicine; or

(iii) rongoā Māori; or

(iv) any indigenous plant or animal materials.

(b) to issue guidelines and give advice where requested by the Regulatory Authority as to;

(i) the classification of complementary and alternative medicinal products; or

(ii) the requirements of the individual tiers of the risk-based approach; or

(iii) traditional or scientific evidence.

(c) to provide advice to the Authority on;

(i) products or ingredients to be included in the black-list at Schedule 1; or

(ii) international regulators to be approved under section 20; or

(iii) published materials to be approved under section 21.

(d) any other function that the Minister assigns to the Expert Advisory Committee by written notice.[1169]

18 Designation of Māori Advisory Committee

(1) The Authority may, by written notice given to an applicable committee, designate that committee as the Māori Advisory Committee for the purposes of this Part.

(2) An applicable committee for the purposes of subsection (1) is;

(a) the Māori Advisory Committee appointed under section 225 Patents Act 2013; or

(b) the Māori Trade Marks Advisory Committee appointed under section 177 Trade Marks Act 2002; or

[1168] Compare: Human Assisted Reproductive Technology Act 2004, ss27, and 33-34.
[1169] Compare: Human Assisted Reproductive Technology Act 2004, ss28 and 35.

(c) Ngā Kaihautū Tikanga Taiao, the Environmental Protection Authority Māori Advisory Committee established under section 18 Environmental Protection Authority Act 2011; or

(d) any other Māori advisory committee established under legislation, which reflects a balanced view of Māori interests and handles matters related to Māori rights over traditional knowledge, flora and fauna.

(3) Each meeting of the Māori Advisory Committee may be attended by the chairperson of the Expert Advisory Committee or a member of the Expert Advisory Committee nominated by the chairperson for the meeting, but a person attending under this subsection is not a member of the Māori Advisory Committee.[1170]

19 Functions of the Māori Advisory Committee

(1) The Māori Advisory Committee has the following functions:

(a) to provide guidelines for the use of Māori traditional knowledge in complementary and alternative medicinal products:

(b) to provide guidelines for the use of any indigenous flora or fauna in complementary and alternative medicinal products:

(c) to provide advice to the Expert Advisory Committee on any of the matters at section 17(1)(a):

(d) to provide advice to the Expert Advisory Committee on any commercialisation and classification of rongoā Māori:

(e) any other function that the Expert Advisory Committee assigns to the Māori Advisory Committee by written notice.[1171]

20 Authority may declare approved international regulators

(1) The Authority may, by notice in the *Gazette*, and by listing the regulator in Schedule 2, declare an international regulator to be an approved international regulator—

(a) for a specified purpose under this Act or provisions of this Act; and

(b) for a specified period or not.

(2) The Authority may only declare an international regulator to be an approved international regulator—

(a) where the international regulator meets or exceeds the relevant principles of this Act; and

(b) where the international regulator makes decisions in respect of similar products upon a risk-based scheme, to a similar, or more robust standard than prescribed in this Act.[1172]

[1170] Compare: Human Assisted Reproductive Technology Act 2004, s27.

[1171] Compare: Environmental Protection Authority Act 2011, s19; Patents Act 2013, s226; Trade Marks Act 2002, s178.

[1172] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl9.

21 Authority may declare approved published materials

(1) The Authority may, by notice in the *Gazette*, and by listing the materials in Schedule 3, declare published materials to be approved published materials—

(a) for a specified purpose under this Act or provisions of this Act; and

(b) for a specified period or not.

(2) The Authority may only declare published materials to be approved published materials—

(a) where the published materials meet or exceed the relevant principles of the Act; and

(b) where the published materials are based on reasonable scientific evidence; or

(c) where the published materials document a history of safe use.

(3) For the purposes of subsections (1) and (2), published materials may include, but are not limited to—

(i) monographs; and

(ii) national formulary; and

(iii) pharmacopoeiae; and

(iv) traditional knowledge databases; and

(v) traditional medicine databases.[1173]

22 Regulations

(1) The Governor-General may, by Order in Council made on the recommendation of the Minister, make regulations—

(a) adding a complementary and alternative medicinal product or ingredient to the black-list in Schedule 1 if the Minister is satisfied that the product or ingredient does not meet the standard for safety under the risk-based approach:

(b) amend Schedule 2 by—

(i) adding an approved international regulator to, or removing an approved international regulator from, the schedule; or

(ii) amending a condition or limit on an approved international regulator in the schedule.

(c) amending Schedule 3 by—

(i) adding an approved published material to, or removing an approved published material from, the schedule; or

[1173] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl9.

(ii) amending a condition or limit on an approved published material in the schedule.

(d) prescribing requirements for the labelling or packaging of complementary and alternative medicinal products; or

(e) prescribing requirements for the advertising of complementary and alternative medicinal products; or

(f) prescribing standards or guidelines for scientific evidence or traditional evidence; or

(g) prescribing standards or guidelines for efficacy claims; or

(h) prescribing standards or guidelines for the classification or reclassification of complementary and alternative medicinal products; or

(i) prescribing the manner in which applications for classification must be made; or

(j) prescribing guidelines on good manufacturing practices and quality control processes for complementary and alternative medicinal products; or

(k) prescribing the requirements relating to access of all publicly available information; or

(l) providing for any other matters contemplated by this Act, necessary for its administration, or for giving effect to any provision of this Act.[1174]

Part 4

Enforcement

23 Misleading and deceptive conduct generally

No person shall, in trade, engage in conduct in relation to complementary and alternative medicinal products that is misleading or deceptive or is likely to mislead or deceive.[1175]

24 Misleading conduct in relation to complementary and alternative medicinal products

No person shall, in trade, engage in conduct that is liable to mislead the public as to the nature, manufacturing process, characteristics, suitability for a purpose, or quantity of complementary and alternative medicinal products.[1176]

25 Unsubstantiated representations

(1) A person must not, in trade, make an unsubstantiated representation.

[1174] Compare: Natural Health and Supplementary Products Bill 2011 (324-2), cl47.
[1175] Compare: Fair Trading Act 1986, s9.
[1176] Compare: Fair Trading Act 1986, s10.

(2) A representation is **unsubstantiated** if the person making the representation does not, when the representation is made, have reasonable grounds for the representation, irrespective of whether the representation is false or misleading.

(3) This section does not apply to a representation that a reasonable person would not expect to be substantiated.

(4) In this section, **representation** means a representation that is made—

(a) in respect of complementary and alternative medicinal products; or

(b) in connection with the supply or possible supply of complementary and alternative medicinal products; or

(c) in connection with the promotion by any means of the use of complementary and alternative medicinal products.[1177]

26 False or misleading representations

(1) No person shall, in trade, in connection with the supply or possible supply of complementary and alternative medicinal products or with the promotion by any means of the use of complementary and alternative medicinal products—

(a) make a false or misleading representation that complementary and alternative medicinal products are of a particular kind, standard, quality, grade, quantity, composition, style, or model, or have had a particular history or particular previous use; or

(b) make a false or misleading representation that complementary and alternative medicinal products have any sponsorship, approval, endorsement, performance characteristics, accessories, uses, or benefits; or

(c) make a false or misleading representation with respect to the price of any complementary and alternative medicinal products; or

(d) make a false or misleading representation concerning the need for any complementary and alternative medicinal products; or

(e) make a false or misleading representation concerning the place of origin of complementary and alternative medicinal products.[1178]

27 Offences

(1) Every person who contravenes a provision of Part 1, Part 2, or sections 24-26 (except section 23), commits an offence and is liable on conviction—

(a) in the case of an individual, to a fine not exceeding $200,000; and

(b) in the case of a body corporate, to a fine not exceeding $600,000.[1179]

28 Defences

[1177] Compare: Fair Trading Act 1986, s12A.
[1178] Compare: Fair Trading Act 1986, s13.
[1179] Compare: Fair Trading Act 1986, s40.

(1) Subject to this section, it is a defence to a prosecution for an offence against section 27 if the defendant proves—

(a) that the contravention was due to a reasonable mistake; or

(b) that the contravention was due to reasonable reliance on information supplied by another person; or

(c) that—

(i) the contravention was due to the act of another person, or to an accident or to some other cause beyond the defendant's control; and

(ii) the defendant took reasonable precautions and exercised due diligence to avoid the contravention.

(2) For the purposes of subsection (1)(b) and (c), the term another person does not include—

(a) a servant or agent of the defendant; or

(b) where the defendant is a body corporate, a director, servant or agent of the defendant.

(3) A defendant is not, without the leave of the District Court, entitled to rely on the defence provided by subsection (1)(b) that the contravention was due to reasonable reliance on information supplied by another person, or by subsection (1)(c)(i) that the contravention was due to the act of another person, unless the defendant has, not later than 7 days before the date on which the hearing of the proceedings commences, served on the prosecutor a notice in writing identifying that person.

(4) It is a defence to a prosecution for an offence against section 27, or to any other proceedings under this Part, in relation to a contravention of a provision of this Act committed by the publication of an advertisement, if the defendant proves—

(a) that the defendant's business is publishing or arranging for the publication of advertisements; and

(b) that the defendant received the advertisement, or the information contained in the advertisement, as the case may be, in the ordinary course of that business and did not know and had no reason to suspect that the publication of the advertisement or the publication of the advertisement containing the information, as the case may be, would constitute a contravention of the provision.[1180]

29 Injunctions

(1) The court may, on the application of the Authority or any other person, grant an injunction restraining a person from engaging in conduct that constitutes or would constitute any of the following—

(a) a contravention of any of the provisions of Part 1, Part 2, or sections 23-26:

(b) any attempt to contravene such a provision:

[1180] Compare: Fair Trading Act 1986, s44.

(c) facilitating in any way the contravention of such a provision.

(2) The court may at any time rescind or vary an injunction granted under this section.

(3) Where an application is made to the court under this section for the grant of an injunction restraining a person from engaging in conduct of a particular kind the court may—

(a) if it is satisfied that the person has engaged in conduct of that kind, grant an injunction restraining the person from engaging in conduct of that kind; or

(b) if in the opinion of the court it is desirable to do so, grant an interim injunction restraining the person from engaging in conduct of that kind, whether or not it appears to the court that the person intends to engage again, or continue to engage in conduct of that kind.[1181]

30 Order to disclose information or publish advertisement

(1) Where, on the application of the Authority, the court is satisfied that a person has engaged in conduct constituting a contravention of any of provisions of Part 1, Part 2, or sections 23-26, the court may make either or both of the following orders:

(a) an order requiring that person, or any other person involved in the contravention, to disclose, at that person's own expense, to the public, or to a particular person or to persons included in a particular class of persons, in such manner as is specified in the order, such information, or information of such a kind, as is so specified, being information that is in the possession of the person to whom the order is directed or to which that person has access:

(b) an order requiring that person, or any other person involved in the contravention, to publish, at that person's own expense, in such manner and at such times as are specified in the order, corrective statements the terms of which are specified in, or are to be determined in accordance with, the order.

(2) The court may hear and determine an application under subsection (1) in conjunction with any other proceedings under either of sections 27 or 29.[1182]

31 Enforceable undertakings

(1) The Authority may accept a written undertaking given by, or on behalf of, a person in connection with any matter relating to the enforcement of this Act.

(2) The person may withdraw or vary the undertaking with the consent of the Authority.

(3) If the Authority considers that a person who has given an undertaking under subsection (1) has breached a term of that undertaking, the Authority may apply to the court for an order under subsection (4).

(4) The court may make any of the following orders if it is satisfied that the person has breached a term of the undertaking:

(a) an order directing the person to comply with the term:

[1181] Compare: Fair Trading Act 1986, s41.

[1182] Compare: Fair Trading Act 1986, s42.

(b) an order directing the person to pay to the Crown an amount not exceeding the amount of any financial benefit that the person has obtained directly or indirectly and that is reasonably attributable to the breach:

(c) any order that the court thinks appropriate directing the person to compensate any other person who has suffered loss or damage as a result of the breach:

(d) an order for any consequential relief that the court thinks appropriate.[1183]

32 Management banning orders

(1) A District Court may make a management banning order against an individual who—

(a) has, on at least 2 separate occasions within a 20-year period, committed an offence against section 27; or

(b) is, or was at the time of the commission of the offence, a director of, or concerned in the management of, an incorporated or unincorporated body that has, on at least 2 separate occasions within a 20-year period, committed an offence against section 27.

(2) The court may make the order only if it is satisfied that the order is necessary to protect the public from the risk that the person, or any incorporated or unincorporated body of which the person is a director, or the management of which the person is concerned in, will commit further offences against section 27.[1184]

[1183] Compare: Fair Trading Act 1986, ss46A and 46B.

[1184] Compare: Fair Trading Act 1986, s46C.

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